

PROJECT BIOSHIELD: LINKING BIOTERRORISM THREATS AND COUNTERMEASURE PROCUREMENT TO ENHANCE TERRORISM PREPAREDNESS

HEARING BEFORE THE SUBCOMMITTEE ON EMERGENCY PREPAREDNESS, SCIENCE, AND TECHNOLOGY OF THE COMMITTEE ON HOMELAND SECURITY HOUSE OF REPRESENTATIVES ONE HUNDRED NINTH CONGRESS FIRST SESSION

JULY 12, 2005

Serial No. 109-29

Printed for the use of the Committee on Homeland Security



Available via the World Wide Web: <http://www.gpoaccess.gov/congress/index.html>

U.S. GOVERNMENT PRINTING OFFICE

27-217 PDF

WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2250 Mail: Stop SSOP, Washington, DC 20402-0001

COMMITTEE ON HOMELAND SECURITY

CHRISTOPHER COX, California, *Chairman*

DON YOUNG, Alaska	BENNIE G. THOMPSON, Mississippi
LAMAR S. SMITH, Texas	LORETTA SANCHEZ, California
CURT WELDON, Pennsylvania	EDWARD J. MARKEY, Massachusetts
CHRISTOPHER SHAYS, Connecticut	NORMAN D. DICKS, Washington
PETER T. KING, New York	JANE HARMAN, California
JOHN LINDER, Georgia	PETER A. DEFazio, Oregon
MARK E. SOUDER, Indiana	NITA M. LOWEY, New York
TOM DAVIS, Virginia	ELEANOR HOLMES NORTON, District of Columbia
DANIEL E. LUNGREN, California	ZOE LOFGREN, California
JIM GIBBONS, Nevada	SHEILA JACKSON-LEE, Texas
ROB SIMMONS, Connecticut	BILL PASCRELL, JR., New Jersey
MIKE ROGERS, Alabama	DONNA M. CHRISTENSEN, U.S. Virgin Islands
STEVAN PEARCE, New Mexico	BOB ETHERIDGE, North Carolina
KATHERINE HARRIS, Florida	JAMES R. LANGEVIN, Rhode Island
BOBBY JINDAL, Louisiana	KENDRICK B. MEEK, Florida
DAVE G. REICHERT, Washington	
MICHAEL MCCAUL, Texas	
CHARLIE DENT, Pennsylvania	

SUBCOMMITTEE ON EMERGENCY PREPAREDNESS, SCIENCE, AND TECHNOLOGY

PETER T. KING, New York *Chairman*

LAMAR S. SMITH, Texas	BILL PASCRELL, JR., New Jersey
CURT WELDON, Pennsylvania	LORETTA SANCHEZ, California
ROB SIMMONS, Connecticut	NORMAN D. DICKS, Washington
MIKE ROGERS, Alabama	JANE HARMAN, California
STEVAN PEARCE, New Mexico	NITA M. LOWEY, New York
KATHERINE HARRIS, Florida	ELEANOR HOLMES NORTON, District of Columbia
DAVE G. REICHERT, Washington	DONNA M. CHRISTENSEN, U.S. Virgin Islands
MICHAEL MCCAUL, Texas	BOB ETHERIDGE, North Carolina
CHARLIE DENT, Pennsylvania	BENNIE G. THOMPSON, Mississippi (<i>Ex Officio</i>)
CHRISTOPHER COX, California (<i>Ex Officio</i>)	

CONTENTS

	Page
STATEMENTS	
The Honorable Peter T. King, a Representative in Congress From the State of New York, and Chairman Subcommittee on Emergency Preparedness, Science, and Technology	1
The Honorable Bill Pascrell, Jr., a Representative in Congress From the State of New Jersey, and Ranking Member, Subcommittee on Emergency Preparedness, Science and Technology	3
The Honorable Christopher Cox, a Representative in Congress From the State of California, and Chairman, Committee on Homeland Security: Prepared Opening Statement	24
The Honorable Bennie G. Thompson, a Representative in Congress From the State of Mississippi, and Ranking Member, Committee on Homeland Security	4
The Honorable Donna M. Christensen, a Delegate From the U.S. Virgin Islands	29
The Honorable Charlie Dent, a Representative in Congress From the State of Pennsylvania	31
The Honorable Norman D. Dicks, a Representative in Congress From the State of Washington	42
The Honorable Bob Etheridge, a Representative in Congress From the State of North Carolina	26
The Honorable Jane Harman, a Representative in Congress From the State of California	32
The Honorable Nita M. Lowey, a Representative in Congress From the State of New York	38
The Honorable Michael McCaul, a Representative in Congress From the State of Texas	37
The Honorable Stevan Pearce, a Representative in Congress from the State of New Mexico	34
The Honorable Dave G. Reichert, a Representative in Congress From the State of Washington	41
The Honorable Rob Simmons, a Representative in Congress From the State of Connecticut	35
The Honorable Curt Weldon, a Representative in Congress From the State of Pennsylvania	27
WITNESSES	
PANEL I	
Ms. Karen T. Morr, Acting Assistant Secretary, Office of Information Analysis, Information Analysis and Infrastructure Protection, Directorate, Department of Homeland Security: Oral Statement	5
Prepared Statement	7
The Honorable Stewart Simonson, Assistant Secretary, Office of Public Health Emergency Preparedness, Department of Health and Human Services: Oral Statement	15
Prepared Statement	17

IV

	Page
Dr. John Vitko, Jr., Director, Biological Countermeasures Portfolio, Directorate of Science and Technology, Department of Homeland Security:	
Oral Statement	10
Prepared Statement	12

PANEL II

Dr. Marcus Eugene Carr, Jr., Executive Director, Clinical Research- Hemostasis, Novo Nordisk, Inc.:	
Oral Statement	44
Prepared Statement	45
Mr. Michael Greenberger, Director, Center for Health and Homeland Security, University of Maryland School of Law:	
Oral Statement	49
Prepared Statement	51
Mr. Richard Hollis, Chief Executive Officer, Hollis-Eden Pharmaceuticals, Inc.:	
Oral Statement	54
Prepared Statement	56
Mr. James A. Joyce, Chairman and Chief Executive Officer, Aethlon Medical, Inc.:	
Oral Statement	64
Prepared Statement	66
Mr. David P. Wright, President & Chief Executive Officer, PharmAthene, Inc.:	
Oral Statement	72
Prepared Statement	73
Ms. Nancy Wysenski, President, EMD Pharmaceuticals:	
Oral Statement	67
Prepared Statement	69

FOR THE RECORD

Mr. John Vitko Responses to Questions From the Honorable Mike Rogers	86
--	----

**PROJECT BIOSHIELD:
LINKING BIOTERRORISM THREATS AND
COUNTERMEASURE PROCUREMENT TO
ENHANCE TERRORISM PREPAREDNESS**

Tuesday, July 12, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON EMERGENCY PREPAREDNESS,
SCIENCE, AND TECHNOLOGY,
Washington, DC.

The subcommittee met, pursuant to call, at 9:33 a.m., in Room 2118, Rayburn House Office Building, Hon. Peter King [chairman of the subcommittee] presiding.

Present: Representatives King, Weldon, Simmons, Pearce, Reichert, McCaul, Dent, Cox (ex officio), Pascrell, Dicks, Harman, Lowey, Norton, Christensen, Etheridge and Thompson (ex officio).

Mr. KING. The subcommittee will come to order.

Good morning. Let me first welcome our distinguished witnesses and say how much we appreciate your appearance before us today.

The purpose of today's hearing is to evaluate the Department of Homeland Security and Health and Human Services' implementation of the Project BioShield Act of 2004. Initially proposed by the President in his State of the Union address in 2003 and enacted into law exactly 1 year ago, BioShield was designed to address the lack of a commercial market for countermeasures against CBRN weapons, creating incentives for biotechnology and pharmaceutical companies to invest and do research in the development of such products. This hearing is not the first on BioShield's implementation nor, I am afraid, will it be the last.

Various House and Senate committees have held numerous committees examining the Department of Health and Human Services BioShield responsibilities, effectiveness of BioShield's market incentives and the need for new legislation to address the need for additional private sector concerns such as liability issues, intellectual property rights and the so-called "valley of death," which is the transition from basic research to countermeasure production. This hearing, however, is different. It will focus on the critical yet relatively unexamined responsibilities of the Department of Homeland Security under BioShield.

Among other things, the Department of Homeland Security is responsible for assessing and determining which agents present material threats to our Nation's security. Such assessments and determinations are central to BioShield's success. They dictate which

specific countermeasures may be eligible for procurement, the specific requirements and whether they are appropriate for inclusion in our Nation's strategic national stockpile, a national repository of countermeasures for use in the event of a public health emergency.

The importance of medical countermeasures cannot be underestimated. The events of September and October, 2001, made it very clear that terrorism, indeed bioterrorism, is a serious threat to our Nation and the world. The anthrax mailings of 2001 killed five people and required thousands to take post-exposure prophylaxes. If there had not been effective countermeasures against that particular strain of anthrax, the death toll may have been higher.

Effective countermeasures exist for few of the biological threats deemed the most dangerous by the Centers for Disease Control and Prevention. The paucity of such countermeasures stems from the lack of a significant commercial market. Of course, diseases such as Marburg and Ebola occur so infrequently in nature biotechnology and pharmaceutical companies have little incentive to invest the millions of dollars required to bring preventive new treatments or vaccines to market.

Experts generally agree that the consequences of a bioterror attack could be devastating. Such an attack could lead to incalculable fatalities and casualties and sow significant fear in the population, lead to a substantial reduction in interstate and probably international commerce, cause social disruption and severely impact our Nation's economy.

Quite frankly, we cannot afford to fail in developing effective countermeasures against such attacks. Having an appropriate stockpile of countermeasures—for example, vaccines, therapeutics and devices—is critical to our Nation's medical preparedness. To that end, I look forward to testimony that may clarify many of my questions regarding BioShield implementation.

One of the roles of the Directorate for Information Analysis and Infrastructure Protection and Science and Technology within DHS is conducting material threat assessments and determinations.

What is the DHS process for prioritizing which agent besides those identified by the CDC as Category A agents warrant such assessments and determinations?

What is the quality of the threat information used by the Department to fulfill its assessment and determination responsibilities, how the Department, given the diversity of potential agents and increasing ability to modify or predict them, will predict and or emerging threats, whether the Department's threat assessment and determination process permits adequate consideration, a board's determination or overemphasizes the so-called one-bug/one-drug approach.

Whether the Department's assessment and determination process permits adequate consideration of medical devices.

Whether the Department's assessment and determination process places an undue premium on vaccines at the expense of anti-infectives, such as post-exposure therapeutics such as antibiotics.

So I want to thank all our witnesses for being here today. I look forward to your testimony.

With that, I recognize the gentleman from New Jersey, the distinguished ranking member of the subcommittee, Mr. Pascrell.

Mr. PASCRELL. Thank you, Mr. Chairman; and thank you for holding what I consider to be a very critical oversight hearing on the implementation of Project BioShield.

This program was designed to encourage the private sector to develop and produce medical countermeasures to combat the effects of potential chemical, biological as well as radiological or nuclear attacks on American soil. So this is a very vital undertaking and one that must be constantly monitored with aggressive vigilance. Indeed, we must insure that the Federal money dedicated to this program is being spent wisely and that Project BioShield is performing up to its intended capabilities. We must do this because the somber reality of our world today is there are a great many people who wish to do us harm and the threat of a WMD attack in the United States is very real.

Remember, it has already happened. In October, 2001, anthrax attacks were launched from my home State of New Jersey. Two weeks ago, a group of 80 arms control and security experts released a survey commissioned by Senator Lugar of Indiana stating that they believe there is a 70 percent chance of a WMD attack in the next 10 years.

While we all agree that we should focus our efforts on preventing any future attack, we must also insure that our citizens and our first responders are adequately protected should an attack take place. That is the goal behind the program.

Congress created Project BioShield in 2004 to expedite terrorism-related procurement hiring and the awarding of research grants. Subsequently, Congress appropriated a great deal of money from 2004 to 2013, with a maximum of \$890 million to be allotted in fiscal year 2004. In November of last year, the Department of Health and Human Services awarded the first contract of \$877.5 million for 75 million doses of a new type of anthrax vaccine. Future possible directions for Project BioShield include smallpox vaccines, anti-radiation treatments, antitoxins and vaccine in the next generation of plague vaccine.

While this work is enormously important, we have some problems, and we must face them now. The private sector maintains continued reluctance to participate in the program. One reason for this is that vaccines for these diseases are inherently risky. Currently, there are no liability protections for companies who wish to participate in the program. This is an issue we need to discuss because, without robust private sector involvement, Project BioShield will fail.

We also have to look at why many companies view the request for proposals aspect of the program so difficult to navigate, so unclear in direction.

Likewise, I am interested in assessing whether the Department of Homeland Security and the Department of Health and Human Services work effectively together. How many times have we heard that question? That many Federal agencies don't even talk to each other as answer is an absolute disgrace, unacceptable to this chairman, unacceptable to this ranking member, unacceptable to everybody on this committee. There is no excuse if that is happening, and it is. So we want to know if they are working effectively in for-

mulating a response strategy and in developing new counter-measures.

Since DHS has the lead role in securing the homeland and its supporting role in Project BioShield, it is vital that this committee continues to conduct oversight into the program. We will do that. Homeland Security is a partnership. It is a partnership between the Federal Government, the State and local governments. It is a partnership between government and industry. If the current program does not provide adequate incentives for industry to participate, then we need to reevaluate the program to make sure we will meet all of our needs.

Thank you, Chairman King, for holding this hearing; and I look forward to hearing from our distinguished panelists. Thank you.

Mr. KING. Thank you, Mr. Pascrell.

The gentleman from Mississippi, the Ranking Member, Mr. Thompson.

Mr. THOMPSON. Thank you very much, Mr. Chairman. I welcome the witnesses who are going to offer testimony at this very important hearing this morning.

The very real threat of a chemical, radiological or nuclear attack is one that government must take seriously and act on quickly and effectively. It was in this spirit that Congress passed the BioShield Act of 2004. BioShield, though, is only the beginning of a continued effort to protect our citizens from this continued threat. The BioShield program has had one partial success. It is helping to meet the needs required to counter the threat of anthrax. Even in this area, we are not seeing the necessary development and stockpiling that BioShield was designed to produce.

HHS awarded an \$877 million contract for 75 million doses of an anthrax vaccine, yet it does not expect to receive any doses until 2006. In the meantime, HHS has paid \$125 million for 5 million doses of a less effective anthrax countermeasure from another vendor. What does it take to get it right? We will talk a little bit more about that in some of the questions that I have for the witnesses.

One major problem, as I have observed, is that the Department of Homeland Security has only completed four material threat assessments in the last year. The Center for Disease Control has identified 60 pathogens that they consider dangerous and could be used as weapons. Each pathogen requires a material threat assessment to begin the BioShield process. We have no chance of procuring countermeasures for these pathogens if the Department only does four assessments in a year.

Mr. Chairman, I appreciate you calling this hearing today on this important topic. I hope the testimony we hear today will insure that BioShield fulfills the mission for which Congress intended. I yield back.

Mr. KING. Thank you, Mr. Thompson.

I will introduce our first panel. We have three witnesses:

Karen Morr, the Acting Assistant Secretary for Office of Information Analysis in DHS.

Dr. John Vitko, the Director of Biological Countermeasures Portfolio, Directorate of Science and Technology of the Department of Homeland Security.

The Honorable Stewart Simonson, Assistant Secretary, Office of Public Health Emergency Preparedness, Department of Health and Human Services.

Mr. KING. Our first witness will be Ms. Morr. You are recognized for 5 minutes.

STATEMENT OF KAREN T. MORR

Ms. MORR. Good morning. Thank you, Chairman King, Representative Thompson, Representative Pascrell and distinguished members of the committee. I thank you for inviting me here today to talk with you about the Information Analysis Office and our expertise and our threat assessments and how we support units throughout DHS as well as our Federal, State and local partners.

I have been with IA since its standup in March of 2003, and I am proud to serve with the men and women of IA who have worked hard to institutionalize an intelligence capability for the Department. We are well on our way to developing a Department that conducts operations and makes decisions informed by the full spectrum of information and intelligence available to DHS.

I would like to start first by describing the general threat and then discuss our processes and products, particularly those dealing with bioterrorism.

The Department takes seriously the threat of bioterrorism. Before we became all familiar with al-Qa'ida and the events of 9/11, groups such as Aum Shinrikyo began employing biological agents in attacks. After 9/11, al-Qa'ida expressed its intent to pursue biological weapons. Bin Laden himself referenced WMD as a religious duty all the way back in 1998.

Al-Qa'ida documents recovered from a training camp in Afghanistan show interest in a variety of biological agents and mentioned plague, anthrax, cholera and tularemia. Although our military operations in the region probably disrupted ongoing biological activity, it is unlikely that such a setback will deter the pursuit of these weapons. In fact, it is clear to the intelligence community that the intent is there. It is up to the intelligence community, including IA, to be constantly on guard for indicators of biological production, enhanced capabilities and operational planning.

In order to fulfill our responsibility, IA regularly collaborates with the National Counterterrorism Center, CIA, FBI, on sharing all sorts of intelligence relating to biological and bioterrorist threats. As members of the intelligence community, we participate regularly in interagency threat assessments. Our analysts coordinate these homeland-focused analyses on the current as well as the emerging biological threats, and we note our differences with the rest of the community when they occur.

Our primary mission, however, is to provide as much relevant information as possible to our Federal, State and local partners so they understand the nature of this threat and can identify and report suspicious activities that could be considered preoperational indicators of a bioterrorist attack.

IA has established a dedicated chemical, biological, radiological, nuclear and explosives analytical team in our Assessments Division, and they are explicitly devoted to the evaluation of all-source information on these threats and capabilities. Our analysis is tai-

lored to the DHS customers, daily support to the Secretary, Homeland Security Operations Center, the Science and Technology Directorate, the Border and Transportation Security Directorate, State and local customers.

Our team is staffed with analysts experienced in intelligence and tradecraft as well as the subject matter of their portfolio. We have complemented these analysts with biological, chemical and nuclear subject matter experts who are on detail from various Department of Energy National Laboratories through an arrangement with the Science and Technology Directorate.

Generally our analysts are engaged in two categories of analytic products. This is what I would call our bread and butter.

The first are typical threat assessments, which are written on known actors and are based on specific intelligence. To determine threat, we examine an actor's capability and intent. We assess capability based on factors such as the actor's level of skill or knowledge, their ability to acquire a biological agent, the materials necessary to grow the agent and their capacity to effectively disseminate a biological agent. For intent, in addition to the actor's desire to simply use biological weapons, we discern which agents they are more likely to pursue, their preferred method of deployment and which targets they intend to attack.

We also perform feasibility assessments. Intelligence is never complete or all-knowing, and we cannot wait until intelligence is received in order to consider plausible scenarios or the impact of a particular technique or technology on a bioterrorist's capability. To move beyond this limitation, IA, in partnership with S&T, conducts assessments of biological processes, emerging technologies and techniques and determines their feasibility for use in a bioterrorism event. These assessments include indicators that will help to identify if a particular venue begins to unfold so we can prevent or disrupt the events before they occur.

In conjunction with these classified feasibility assessments, we are producing unclassified excerpts with the indicators which are distributed widely to local, Federal, State officials, as well as to the private sector to enhance their awareness and to increase suspicious activity reporting and trigger investigations where necessary.

We recently published Indicators of Terrorist Production of Anthrax in June, 2005, with the knowledge that it will be at the local level where these indicators of operational activity are most embedded.

In terms of our tailored support, under the BioShield legislation DHS is charged with assessing current and emerging threats and determining which of such agents present a material threat against the United States population.

The Science and Technology Directorate, supported by IA, has been conducting material threat assessments and material threat determinations in order to guide near-term BioShield requirements and acquisitions. These material threat assessments are intelligence informed. However, they are not based on specific intelligence or a known actor. Rather, they are speculative in the sense that they represent a best estimate of how—

Mr. KING. Ms. Morr, if you could try to wrap it up in the next minute or two, because we do have two panels of witnesses today.

Ms. MORR. Okay, I am sorry.

Mr. KING. That is all right.

Ms. MORR. Currently, the MTAs are drafted by S&T, and IA provides assessment before it is provided to HHS. We insure that the assessment reflects what IA assesses is the general capability of—terrorist capabilities—that are pursuing biological weapons. This is an important consideration because, if the MTA overestimates the capability, the projected casualties and medical countermeasures will be artificially inflated. On the other hand, if the adversary is underestimated, we could be unprepared. So we perform a contribution into the S&T MTA.

In summary, I guess I will just conclude by saying that IA has a robust and complementary chemical and biological analytic effort. We are partnering across DHS units with our State and local partners; and we are providing actionable, accurate expert assessments across the board.

Mr. KING. Thank you. Sorry for the interruption, but we have—
[The statement of Ms. Morr follows:]

PREPARED STATEMENT OF KAREN MORR

Introduction

Good morning Chairman King, Representative Pascrell, and distinguished members. Thank you for the privilege to discuss the role of the Department of Homeland Security's (DHS) Office of Information Analysis (IA) in the threat assessment process and how these assessments are used to support our DHS operational components as well as our Federal, State, and local partners.

The Department takes seriously the threat of bioterrorism. On a routine basis IA discusses with colleagues at the National Counterterrorism Center, CIA, and FBI, all-source intelligence on bioterrorist threats and potential operatives, their plans, and activities. Also, as members of the Intelligence Community we participate in interagency threat assessments. Our analysts coordinate their homeland-focused analysis on the current as well as the emerging biological threats, noting our differences with the rest of the Intelligence Community, when they occur.

Our primary mission is to provide as much relevant information as possible to our Federal, State, and local partners so they understand the nature of this threat and can identify and report suspicious activities that could be considered pre-operational indicators of a bioterrorist attack. We also provide intelligence-derived threat information to Federal agencies so they can best tailor research, development, and program planning to the current threat streams.

Today I have been asked to discuss the process by which we develop our threat assessments and analytical products, including those for BioShield. Last month one of our analysts provided some of the Committee members with a classified briefing on the specifics of the current bioterrorist threat to the Homeland. I will not be able to revisit this classified threat assessment in this open forum but we would be happy to provide this information to additional members in a closed session.

IA's Approach to Threat Assessment

IA has established a dedicated chemical, biological, radiological, nuclear, and explosives (CBRNE) analytical team in our Assessments Division explicitly devoted to the evaluation of all-source information on these threats and terrorist capabilities. Our current analysis and more in depth strategic threat assessments are tailored to our DHS customers, including daily support to the Secretary, the Homeland Security Operations Center, and the Science and Technology and Border and Transportation Security Directorates. State and local customers receive threat assessments as credible information becomes available.

Our CBRNE team is staffed with analysts experienced in intelligence analysis and tradecraft as well as the subject-matter of their portfolio. We have complemented these analysts with biological, chemical, and nuclear subject-matter experts on detail from various Department of Energy National Laboratories through an arrangement with the S&T Directorate. These scientists bring deep technical knowledge

that IA analysts leverage daily in their work so we can provide timely and accurate analysis on current WMD-related intelligence and threat information.

On occasion, we require quick access to information that does not reside within IA. In these cases, our analysts are supported to the Biodefense Knowledge Center (BKC)—a 24x7 support cell based at Lawrence Livermore National Laboratory and sponsored by the S&T Directorate. The BKC possesses vast repositories of biological technical information and is able to access SMEs from around the country, such as the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the U.S. Army Medical Research Institute for Chemical Defense (USAMRICD), and the Armed Forces Medical Intelligence Center (AFMIC), in support of a tasking from IA. The BKC compiles the appropriate information and relays it to our analysts who integrate the information into their finished intelligence analysis.

Our analysts regularly collaborate with other intelligence agencies, particularly NCTC, DIA, FBI, and CIA. We also work with experts from government, academic, and private institutions and partner with scientists who keep us abreast of their potential areas of concern and the trends they see. Interaction with outside public and private sector institutions keeps us well-informed of new and emerging technology that may be exploited or misused by malicious actors. For example, IA recently hosted a workshop on emerging biotechnologies and the future biological threat. This provided a forum for non-governmental experts to provide IA with information of which they believe we should monitor.

Our analysts are broadly focused and access a wide array of information in gathering source material for our assessments. They use all-source intelligence, scientific and technical information, terrorist profiles, historical trends, and open source information such as media reports and scientific journal articles. We keep current on foreign State biological weapons program developments as these activities may have implications for future terrorist events. We look at the intent of the enemy, their capabilities, potential scenarios, and attack vectors. Working with counterterrorist experts in the Community, we develop link charts on potential associates here in the United States of operatives abroad who may have received training in WMD capabilities or have knowledge of WMD programs.

Bioterrorism Analytical Products

IA has produced several bioterrorism-related products examining the threat posed by specific actors, the potential misuse of biotechnology, and to alert operators in the field of possible bioterrorism activity. For example, we assessed the implications of the H2N2 influenza shipment in which a U.S. contractor sent a highly virulent strain of influenza to hundreds of laboratories worldwide. We also recently published an Information Bulletin advising State and local law enforcement officials of indicators of covert anthrax production. Generally, our products fall into two categories: threat assessments and feasibility assessments.

Threat Assessments. Threat assessments are written on known actors and are based on specific intelligence. To determine threat, we examine an actor's capability and intent. We calculate capability based on factors such as a particular actor's level of skill or knowledge; their ability to acquire a biological agent and the materials necessary to grow the agent; and their capacity to effectively disseminate a biological agent. For intent, we consider more than just an actor's desire to use biological weapons. We attempt to discern which agents they are more likely to pursue, their preferred method of deployment, and which targets they intend to attack.

Feasibility Assessments. Intelligence is never complete or all-knowing and we cannot wait until intelligence is received in order to consider plausible scenarios or the impact of a particular technique or technology on a bioterrorist's capability. To move beyond this limitation, IA, in partnership with S&T, conducts assessments of biological processes, emerging technologies, and techniques and determines their feasibility for use in a bioterrorism event. These assessments include indicators that will help to identify if a particular scenario begins to unfold so we can prevent or disrupt events before they occur. In conjunction with the feasibility assessment, we are producing unclassified excerpts with the indicators which are distributed widely to local, State, Federal officials as well as the private sector to enhance awareness in the field and to increase suspicious activity reporting and trigger investigations where necessary.

IA also has produced several bioterrorism-specific "red team" products, which explore issues from a terrorist's perspective using nongovernmental experts and creative thinkers. These topics have included terrorist use of genetically modified food and recombinant DNA technologies to damage the U.S. food supply; possible terrorist exploitation of a U.S. flu vaccine shortage; and the safety and security impacts of a pandemic influenza outbreak.

IA Support to BioShield

Under the BioShield legislation, DHS is charged with assessing current and emerging threats of chemical, biological, radiological, and nuclear agents; and determining which of such agents present a material threat against the United States population. S&T, supported by IA, has been conducting Material Threat Assessments (MTAs) and Material Threat Determinations (MTDs) in order to guide near-term BioShield requirements and acquisitions.

MTAs are intelligence-informed; however, they are not based on a specific intelligence or a known actor. Rather, they are speculative and represent a best estimate of how an adversary may create a high-consequence event using the agent/weapon in question. Currently, MTAs are drafted by the S&T and IA provides comments on the assessment before it is provided to HHS. In our review, we ensure that the assessment reflects what IA assesses is the general capability of terrorist groups that are pursuing biological weapons. This is an important consideration; if the MTAs overestimate an adversary's capability, the projected casualties and medical countermeasure requirements will be artificially inflated. On the other hand, if the adversary is underestimated, we could be underprepared and leave a gap in our defenses.

The MTAs result in an estimate of the number of exposed individuals, the geographical extent of the exposure, and other collateral effects. If these consequences are of such a magnitude to be of significant concern to our national security, the Secretary of DHS then issues a formal Material Threat Determination to the Secretary of HHS, which initiates the BioShield process.

To date, one MTA has been completed for anthrax and MTAs for plague, botulinum toxin, tularemia, radiological devices and chemical nerve agents are underway and an MTA for viral hemorrhagic fevers will be initiated next month. MTDs have been approved for four agents: smallpox, anthrax, botulinum toxin, and radiological/nuclear devices. Dr. Vitko will provide more information on MTAs and MTDs and how they are used by HHS.

IA Bioterrorism Initiatives

Now I would like to inform you of some of IA's initiatives to improve our bioterrorism threat knowledge and to pass on that knowledge to operators in the field.

In March of this year we established a working group of twelve senior biological weapons analysts from various Intelligence Community agencies. This group, chaired by IA and vice-chaired by NCTC, was formed to provide intelligence support to the DHS National Biodefense Analysis and Countermeasures Center (NBACC), which is charged with conducting studies and laboratory experiments to fill in information gaps to better understand current and future biological threats.

The working group is initially supporting the first National Biological Risk Assessment—a quantitative analysis of biological agents based on threat, vulnerabilities, and consequences that will enable the U.S. Government to prioritize research and development. After the risk assessment is completed later this year, the group will serve as the focal point for the Intelligence Community interaction with NBACC. The group will provide threat information to NBACC and will review their research conducted in support of the Intelligence Community.

In order to get our information out to our largest user community—local and State law enforcement and first responders, IA, in cooperation with NCTC and the FBI, is providing WMD outreach briefings around the country. These briefings outline the terrorist WMD threat, including descriptions of the types of weapons used and indicators and warnings aimed at increase awareness and reporting. In the near future, we hope to expand these briefings to other audiences such as academia and the private sector to further increase awareness and reporting.

IA will be playing a key role in supplying current intelligence to the National Bio-surveillance Integration System (NBIS) operations center once it begins operation later this summer. NBIS will fuse information on human, plant, and animal health with environmental monitoring of air, food, and water systems. This information will be integrated with threat and intelligence information to provide real-time situational awareness and identify anomalies or trends of concern to the Homeland Security Operations Center.

Conclusion

In sum, IA has developed a robust, but complementary, CBRNE analysis capability with other partners in the Intelligence Community. We remain focused on our unique Departmental niche which is to push as much information as possible to our State and local partners on a timely basis, to focus exclusively on the possibilities of, and potential for, a Homeland-focused attack, and to provide actionable, accurate expert assessments to DHS leadership and operational components.

We are building a unique culture and rewarding experience for our analysts who are comfortable in their intelligence and operational roles and in applying the best scientific knowledge available to the U.S. government to combat the enduring CBRNE threat to the Homeland.

Mr. KING. Dr. Vitko, again, if you can try to keep it to 5 minutes; and the balance of your statement will be made a part of the record.

STATEMENT OF JOHN VITKO, JR., DIRECTOR, BIOLOGICAL COUNTERMEASURES PORTFOLIO DIRECTORATE OF SCIENCE AND TECHNOLOGY, DEPARTMENT OF HOMELAND SECURITY

Mr. VITKO. I will comply.

Good morning, Chairman King, Chairman Cox, Congressman Pascrell and Ranking Member Thompson and distinguished members of the subcommittee. I am pleased to appear before you today to discuss the role that the Department of Homeland Security's threat and risk assessments play in informing and prioritizing BioShield acquisitions and to discuss our close coordination with the Department of Health and Human Services throughout the process.

As you know, the Project BioShield Act of 2004 charges the Secretary of Homeland Security with the responsibility to determine which biological, chemical, radiological and nuclear threats constitute a material threat to our Nation's security.

To fulfill this responsibility, DHS S&T, in partnership with Information Analysis and Infrastructure Protection Directorate, IAIP, has been conducting formal threat risk assessments of the greatest concern to establish plausible high-consequence scenarios.

In this process, IAIP, as you have already heard, in concert with other members of the intelligence community, provides information on the capabilities, plans and intentions of terrorists and other nonstate actors. However, since lack of intelligence on a threat does not mean lack of a threat, S&T, in concert with the appropriate members of the technical community, assesses the technical feasibility of the terrorists being able to obtain, disseminate and produce the agent in question and the resulting vulnerabilities and consequences. This information is used to establish a plausible high-consequence scenario that provides an indication of the number of exposed individuals, the geographical extent of the exposure and other collateral effects. If these consequences are of such a magnitude to be of significant concern to our national security or public health, the Secretary of DHS issues a formal threat determination to the Secretary of HHS, which initiates the BioShield process.

To date, the Secretary of DHS has issued material threat determinations for four agents: anthrax, smallpox, botulinum antitoxin and radiological/nuclear devices. In addition, threat and risk assessments are currently under way and will be completed this year for plague, tularemia, radiological devices and chemical nerve agents; and a threat assessment for viral hemorrhagic fevers will be issued next month in August.

Once a material threat determination has been issued, HHS assesses the potential public health consequences of the identified agent, determines the needs for countermeasures, evaluates the

availability of current countermeasures and the possibility of development of new countermeasures. They are assisted by the inter-agency Weapons of Mass Destruction Countermeasures Subcommittee. Any recommendations issued for the acquisition of a specific countermeasure are evaluated through the interagency process that forms the basis of U.S. government requirements. After approval of these requirements by the Office of Management and Budget, HHS issues a request for proposals and implements and manages the subsequent acquisition process through the delivery of countermeasures through the strategic national stockpile.

Throughout this process DHS works very closely with HHS. HHS subject matter experts participate in threat assessments and risk assessments. HHS, DHS and Department of Defense co-chair the WMD Medical Countermeasures Subcommittee; and HHS keeps DHS informed about the subsequent acquisition processes. These interactions occur at multiple levels, from formal interagency committees through bilateral management interactions to informal but important contact and collaborations amongst the working scientists.

The threat assessments discussed above focus on those CBRN agents widely believed to be of the greatest concerns that guide near-term BioShield acquisition policies. In essence, we have jump-started the process.

DHS S&T is also conducting three activities to guide future rounds of BioShield acquisition. As part of our responsibilities in the President's request for biodefense in the 21st century, we are conducting a formal risk assessment across a wide range of biological threats, including all Category A and B agents from the Centers for Disease Control and Prevention threat list, some Category C agents and a number of potential engineered threats. These risk assessments will be completed by January of 2006 and factor in the technical feasibility of producing and disseminating the threat, the vulnerability of different portions of our society to those threats and the resulting consequences of any such attacks.

Looking still further into the future, we have partnered with HHS and others in formulating and implementing the strategy for anticipating and responding to engineered threats. Together, we have developed and informed them of types of emerging threats that might be within the ability of a terrorist organization to develop the near, mid and longer terms and have laid out a strategy for addressing them.

Realizing that there are still large uncertainties, sometimes factors of 10 to 100 and some of the key parameters underlying these threat and risk assessments, we have established a National Bio-defense and Countermeasure Center to conduct the laboratory experiments needed to reduce these uncertainties. Pending the completion of construction and associated facilities on the four-tear campus in 2008, interim capabilities have been established with other government and private laboratories to begin this vital work.

In summary, the DHS Science and Technology Directorate's threat and risk assessments play a critical role in prioritizing BioShield acquisitions. Throughout the process we work closely with our colleagues at HHS to most effectively couple HHS expertise on

threat and risk with HHS expertise on human health to better protect our Nation.

This concludes my prepared statement. Mr. Chairman, Congressman Cox, Congressman Pascrell, Ranking Member and members of the subcommittee, I thank you for the opportunity to appear before you; and I would be happy to answer any questions you may have.

Mr. KING. Thank you, Dr. Vitko.

[The statement of Mr. Vitko follows:]

PREPARED STATEMENT FOR THE RECORD OF DR. JOHN VITKO, JR.

INTRODUCTION

Good afternoon, Chairman King, Congressman Pascrell and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the role that the Department of Homeland Security's (DHS) threat and risk assessments play in informing and prioritizing BioShield acquisitions and to discuss our close coordination with the Department of Health and Human Services throughout that process.

Before focusing on the Department's specific activities in support of Project BioShield, I would like to put these activities in the broader context of the overall responsibilities and activities of the DHS Biological Countermeasures Portfolio (Bio Portfolio) which I direct. The mission of this Portfolio is to provide the understanding, technologies, and systems needed to anticipate, deter, protect against, detect, mitigate, and recover from possible biological attacks on this nation's population, agriculture or infrastructure.

In addressing this mission, DHS has a leadership role in several key areas and partners with lead agencies in others. Those areas in which the Science and Technology (S&T) Directorate provides significant leadership are:

- Providing an overall end-to-end understanding of an integrated biodefense strategy, so as to guide the Secretary and the rest of the Department in its responsibility to coordinate the nation's efforts to deter, detect, and respond to acts of biological terrorism.
- Providing scientific support to better understand both current and future biological threats and their potential impacts so as to guide the research and development of biodefense countermeasures such as vaccines, drugs, detection systems and decontamination technologies.
- Developing early warning, detection and characterization systems to permit timely response to mitigate the consequence of a biological attack.
- Conducting technical forensics to analyze and interpret materials recovered from an attack to support attribution.
- Operation of the Plum Island Animal Disease Center to support both research and development (R&D) and operational response to foreign animal diseases such as foot and mouth disease.

DHS also supports our partnering departments and agencies with their leads in other key areas of an integrated biodefense: the Department of Health and Human Services (HHS) on medical countermeasures and mass casualty response; the Department of Defense (DoD) on broad range of homeland security/homeland defense issues; the U.S. Department of Agriculture (USDA) on agriculture biosecurity; USDA and HHS on food safety; the Environmental Protection Agency (EPA) on decontamination and on water security; the Department of Justice on bio-terrorism investigations; and the Intelligence Community on threat warnings.

THREAT AND RISK ASSESSMENTS

As noted above, providing threat and risk assessments of both current and future threats and the scientific understanding to improve and refine these assessments is a major responsibility for DHS. These responsibilities are further defined in the BioShield Act of 2004, which charges the Secretary of DHS with the responsibility for determining which threats constitute a Material Threat to the national security or public health of the Nation and in the President's *Biodefense for the 21st Century*, which charges DHS with the lead in "conducting routine capabilities assessments to guide prioritization of our ongoing investments in biodefense-related research, development, planning and preparedness".

Today, I would like to focus on four major activities that we have undertaken to fulfill these responsibilities and that help guide both near and longer-term acquisitions of medical countermeasures:

1. Material Threat Assessments and Determinations in support of near-term Project BioShield procurements;

2. Risk Assessments across a broader range of biological threats;
3. A Strategy for Addressing Emerging Threats (in partnership with the Department of Health and Human Services (HHS) and others);
4. Scientific research to better inform these threat and risk assessments.

Material Threat Assessments and Determinations In Support of Near-Term Project BioShield Procurements

Working with the DHS Directorate for Information Analysis and Infrastructure Protection (IAIP), DHS S&T has been conducting assessments and determinations of biological, chemical, radiological and nuclear agents of greatest concern so as to guide near-term BioShield requirements and acquisitions. In this process, IAIP, in concert with other members of the intelligence community, provides information on the capabilities, plans and intentions of terrorists and other non-state actors. However, since lack of intelligence on a threat does not mean lack of a threat, S&T, in concert with appropriate members of the technical community, also assesses the technical feasibility of a terrorist being able to obtain, produce and disseminate the agent in question. This information is used to establish a plausible high consequence scenario that provides an indication of the number of exposed individuals, the geographical extent of the exposure, and other collateral effects. If these consequences are of such a magnitude to be of significant concern to our national security or public health, the Secretary of DHS then issues a formal Material Threat Determination to the Secretary of HHS, which initiates the BioShield process.

To date, the Secretary of DHS has issued Material Threat Determinations for four “agents”: anthrax, smallpox, botulinum toxin, and radiological/nuclear devices. Additional threat assessments are currently underway for plague, tularemia, radiological devices and chemical nerve agents and a threat assessment for viral hemorrhagic fevers will be initiated next month.

Once a Material Threat Determination (MTD) has been issued, the HHS then assesses the potential public health consequences of the identified agent, determines the need for countermeasures, evaluates the availability of current countermeasures and the possibility of development of new countermeasures. They are assisted by the interagency Weapons of Mass Destruction Medical Countermeasures (WMD-MC) subcommittee. Any recommendations issued for the acquisition of a specific countermeasure are evaluated through interagency processes and form the basis of the U.S. Government requirements. After approval of these requirements by the Office of Management and Budget, the HHS issues a Request for Proposals and implements and manages the subsequent acquisition process through delivery of the countermeasures to the Strategic National Stockpile.

Throughout this process DHS works very closely with HHS. HHS subject matter experts participate in the threat assessments. HHS, DHS, and DoD co-chair the WMD-MC committee. And HHS keeps DHS informed about the subsequent acquisition process. These interactions occur at multiple levels from formal interagency committees (WMD-MC) through bi-lateral management interactions to informal but important contact and collaborations amongst the working scientists.

Risk Assessments Across a Broader Range of Biological Threats

The preceding discussion dealt with threat assessments of those CBRN agents widely agreed to be of greatest concern so as to guide near-term BioShield acquisition processes. As part of its responsibility in the President’s National Biodefense Strategy, DHS is conducting a formal risk assessment of a much broader set of biological agents to help prioritize the nation’s ongoing biodefense activities, including subsequent rounds of BioShield acquisitions. These risk assessments provide a systematic look at the technical feasibility of a broad range of biological threats, the vulnerability of different portions of our society to those threats, and the resulting consequences of any such attacks.

The first such formal risk assessment is due in the winter of 2006, with subsequent assessments due every two years. The scope, process and timescale for this first assessment have been presented to and agreed to by the interagency Biodefense Policy Coordinating Committee co-chaired by the Homeland Security Council and the National Security Council. This assessment is addressing:

- All six category A agents from the Centers for Disease Control and Prevention (CDC) threat list;
- All 12 category B agents;
- Five representative category C agents; and
- A number of candidate drug-resistant and emerging agents.

Key outputs will include:

- A list of bio-threats prioritized by risk;
- A prioritized list of critical knowledge gaps that if closed should reduce risk assessment uncertainty and guide bio-defense research and development; and

- A list of biodefense vulnerabilities that could be reduced by countermeasure development and acquisition.

This risk assessment is being conducted in partnership with the Intelligence Community, the HHS, the Department of Defense, the U.S. Department of Agriculture, the Environmental Protection Agency and others. Two advisory boards, one a Government Stakeholders Advisory Board and the other an Independent Risk Assessment Expert Review Board (academia, industry and government) have been established to provide input and advice.

This and subsequent risk assessments will play a critical role in informing future biodefense programs across all agencies, including BioShield acquisitions and the longer-term medical R&D leading up to such acquisitions.

A Strategy for Addressing Emerging Threats

Much of the biodefense efforts to date have focused on protecting against attacks with bioterrorism agents that can be (or used to be) found in nature. However, rapid advances in biotechnology demand that we also consider the possibility and impact of emerging or engineered agents. e.g. modifications to organisms that increase their resistance to medical countermeasure or make them more difficult to detect. The President's *Biodefense for the 21st Century* assigns the HHS the lead in anticipating such future threats. We, DHS S&T, are partnering with HHS and others in formulating and implementing a strategy for anticipating and responding to such threats.

Based on intelligence information, available literature and expert judgment, we have developed an informed estimate of the types of emerging threats that might be within the ability of a terrorist organization to develop over the near (1–3 years), mid (4–10 years), and longer-terms (10 yrs). We have also examined the impact of these threats on the four pillars of the National Biodefense Policy: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

In this analysis, four elements stand out as essential to an effective defense against emerging threats:

- Threat, vulnerability and risk assessments to prioritize these threats in terms of the difficulty of their development and deployment, as well as their potential consequences;
- Surveillance and detection capabilities to rapidly detect and characterize engineered agents in environmental and clinical samples so as to provide timely guidance in the selection of the appropriate medical countermeasure;
- An expanded range of safe and effective medical countermeasures and an infrastructure to support rapid research, development, test and evaluation (RDT&E) of new medical countermeasures; and
- integrated concepts of operation (CONOPS) for the identification and response to emerging threats. In addition to conducting these assessments, DHS will continue to collaborate with HHS as it leads efforts to anticipate agents and to facilitate the availability of medical countermeasures.

Scientific research to better inform these threat and risk assessments

The threat and risk assessments described above are performed with the best available information. However, there are large uncertainties, sometimes factors of ten to a hundred, in some of the key parameters and hence in the associated risks. One of the major functions of the threat and risk assessments is to identify these critical knowledge gaps, which can differ for different threat scenarios—in one case it can be the minimum amount of agent needed to infect a person; in another case it can be the time that such an agent remains viable (capable of causing an infection) in the air, food or water; and in a third it can be the effect of food processing or water treatment on the agent's viability. Conducting the laboratory experiments to close the critical knowledge gaps is a primary function of DHS's National Biodefense Analysis and Countermeasures Center (NBACC).

Congress has appropriated a total of \$128M for design and construction of NBACC with the necessary biocontainment laboratory space and support infrastructure to conduct these and other experiments. NBACC will be built on the National Interagency Biodefense Campus (NIBC) at Ft. Detrick MD, where its close physical proximity to the DoD's United States Army Medical Research Institute for Infectious Diseases (USAMRIID), the NIH's Integrated Research Facility and the USDA's Foreign Disease-Weed Science Research Unit. NBACC is also collaborating with the Centers for Disease Control and Prevention to further address the critical knowledge gaps. The Record of Decision for NBACC's Final Environmental Impact Statement was signed in January 2005. Design of the facility began in March 2005, with construction scheduled to begin in FY 2006 and be complete by the fourth quarter of FY 2008.

Currently, interim capabilities for both NBACC's biological threat awareness and bioforensic analysis functions have been established with other government and private laboratories to allow vital work in these areas to occur during the NBACC facility's construction.

CONCLUSION

In summary, the DHS Science and Technology Directorate's programs in threat and risk assessment play a critical role in prioritizing both near and longer-term BioShield acquisitions and hence in furthering the Committee's goal of "Linking Bio-terrorism Threats and Countermeasure Procurement to Enhance Terrorism Preparedness". Throughout this process we work closely with our colleagues at HHS through a variety of interagency, bi-lateral, and informal scientist-to-scientist interactions so as to most effectively couple DHS expertise on the threat with HHS expertise on human health to better protect our Nation.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Congressman Pascrell, and Members of the Subcommittee, I thank you for the opportunity to appear before you and I will be happy to answer any questions that you may have.

Mr. KING. Now Secretary Simonson.

STATEMENT OF THE HONORABLE STEWART SIMONSON, ASSISTANT SECRETARY, OFFICE OF PUBLIC HEALTH EMERGENCY PREPAREDNESS, DEPARTMENT OF HEALTH AND HUMAN SERVICE

Mr. SIMONSON. Thank you.

Good morning, Mr. Chairman, Chairman Cox, Mr. Pascrell, Mr. Thompson and other members of the committee. I am Stewart Simonson, Assistant HHS Secretary for Public Health and Emergency Preparedness. I appreciate the opportunity to share with you information on the Department's progress on implementing the Project BioShield Act of 2004 and specifically the linkage between acquisition programs and threat assessments provided by our colleagues at the Department of Homeland Security.

The events of September and October of 2001 made it very clear that terrorism is a serious threat to our Nation and to the world. The Bush Administration and Congress responded forcefully to this threat by strengthening our medical and public health capacities to protect our citizens from future attacks. To encourage the development of new medical countermeasures against threat agents and to speed their delivery, President Bush in his 2003 State of the Union Address proposed—and Congress subsequently enacted—Project BioShield. The \$5.6 billion 10-year Special Reserve Fund was created to assure developers of medical countermeasures that funds would be available for the government to purchase critical products. Since enactment, my office has moved aggressively to fill immediate gaps in our countermeasure armamentarium.

A genuine sense of urgency influences all of our Homeland Security work at HHS, but it is important to note that the successful development and manufacture of safe and effective countermeasure requires an investment of both money and time. No matter how hard we try, some steps in the process cannot be rushed. There is a complex spectrum of effort needed along the research and development pipeline to produce a use able medical countermeasure. Defining specifications for a needed countermeasure often reveals few, if any, candidates in the pipeline. To date, we have been fortunate that some of our highest priority needs for medical counter-

measures could be addressed using the available advanced development products already in the pipeline.

In determining the requirements and evaluating options for medical countermeasure acquisition, the focal point for the U.S. government interagency efforts is the Weapons of Mass Destruction Medical Countermeasure Subcommittee. HHS, along with representatives from the Department of Homeland Security and the Department of Defense, chairs the WMD subcommittee; and stakeholders from throughout the U.S. government are represented on its working groups.

In setting priorities for medical countermeasure acquisitions under Project BioShield, the WMD subcommittee considers a number of factors, the credibility and immediacy of specific threats or driving factors and are informed by material threat assessments conducted by our colleagues at DHS.

Among biological threat agents, smallpox and anthrax are widely recognized as having the greatest potential to cause catastrophic harm. Material threat determinations for these agents were among the first ones made by the Secretary of Homeland Security, along with those for botulinum antitoxin and radiological and nuclear agents. We also can consider the current and projected availabilities of appropriate medical countermeasures as well as the target population for which the countermeasure would be used.

In addition, logistical issues are considered, such as the feasibility of deployments in a medical public health emergency, shelf life, storage life and maintenance requirements.

Project BioShield requires a number of findings by the Secretaries of Homeland Security and HHS prior to an acquisition commencing. These findings include three determinations: first, that there is a material threat against the U.S. population sufficient to affect national security; second, that medical countermeasures are necessary to protect the public health from that material threat; third, that acquiring a specific quantity of a particular medical countermeasure, using the Special Reserve Fund, is appropriate.

These determinations are followed by a joint recommendation to the White House by the two Secretaries. If approved, Congress is notified and HHS executes the acquisition program.

The process that I have outlined has been successfully implemented through contract award three times since the enactment of Project BioShield nearly a year ago. HHS has completed contract awards for acquisitions for next-generation recombinant protective antigen anthrax vaccine, the current-generation licensed anthrax vaccine and the pediatric formulation of potassium iodide. Additionally, the acquisition process is in the final execution phases for several other needed medical countermeasures, including anthrax therapeutics, botulinum antitoxin and a next-generation smallpox vaccine. All of these acquisition programs have been threatened by material threat determinations by DHS.

This robust interagency process mines the expertise in the scientific and intelligence communities to define requirements for medical countermeasures and enables policymakers to identify and evaluate acquisition options to address immediate and future needs.

As we move forward with implementation of Project BioShield, the decisions about priority setting for how best to use the remaining funding will become more challenging and more dependent on guidance from DHS.

I must emphasize that the number of threat agents from which we could guard ourselves is endless. New and emerging threats introduced by man or nature will present continuing challenges. Although we cannot be prepared for every potential threat, we are implementing a strategic approach for identifying and combatting the highest priority threats as assessed in large part by our colleagues at DHS.

In closing, let me say that HHS has a clear mandate from President Bush and Congress to lead the charge in medical countermeasure development. We have already made important strides to address the public health needs of the Nation, but more needs to be done.

Mr. Chairman, I look forward to working with you, Congressman Pascrell and the subcommittee to address the challenges of CBRN preparedness and its impact on public health. I would be happy to answer any questions.

Mr. KING. Thank you for your testimony, Mr. Simonson.

[The statement of Mr. Simonson follows:]

PREPARED STATEMENT OF HON. STEWART SIMONSON

Good morning, Chairman King, Mr. Pascrell, and Subcommittee members. I am Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services (HHS). I appreciate the opportunity to share with you information on the Department's progress in research, development and acquisition programs for medical countermeasures, particularly with regard to the implementation of the Project BioShield Act of 2004 ("Project BioShield"), and in particular, the linkage of our acquisition programs to threat assessment provided by our colleagues at the Department of Homeland Security (DHS). These programs are vital components of our strategy to protect the Nation from threats posed from chemical, biological, radiological and nuclear (CBRN) threats. Defending against such threats is a top priority for the Bush Administration and having an appropriate armamentarium of medical countermeasures is a critical element of the response and recovery component of the President's "21st Century Strategy for Bio-defense." The acquisition and ready availability of medical countermeasures, such as antibiotics, antivirals, monoclonal and polyclonal antibodies against infectious threats, therapies for chemical and radiation-induced illnesses, and vaccines to protect against exposure from biological agents are essential to our Nation's preparedness and response capabilities.

Protecting Americans

The events of September and October 2001 made it very clear that terrorism-indeed bioterrorism-is a serious threat to our Nation and the world. The Bush Administration and Congress responded forcefully to this threat by providing funding to strengthen our medical and public health capacities to protect our citizens from future attacks. Specifically, substantial increases in funding for research, development and acquisition of medical countermeasures against biological threats were directed to the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention's Strategic National Stockpile (SNS or "the Stockpile"). To further encourage the development of new medical countermeasures against chemical, biological, radiological and nuclear agents and to speed their delivery and use should there be an attack, President Bush, in his 2003 State of the Union address proposed and Congress subsequently enacted Project BioShield. The Special Reserve Fund, appropriated with \$5.6 billion was created to assure developers of medical countermeasures that funds would be available to purchase these critical products for use to protect our citizens.

The Strategic National Stockpile Today

The wake-up call that we received in the fall of 2001 highlighted the gaps in our medical countermeasure armamentarium and we immediately began working to ad-

dress them. Although much remains to be done, we have made significant progress in building our Strategic National Stockpile from that time to what we have on-hand today. For example, our smallpox vaccine stockpile has grown from 90,000 ready-to-use doses in 2001 to enough vaccine to protect every man, woman, and child in America. Major strides have been made in building our medical countermeasure reserve against anthrax, plague, and tularemia. We are now able to protect and treat millions of Americans in the event of an attack with one of these agents. We have taken the botulinum antitoxin program started by the Department of Defense in the early 1990s to completion and we are now building our botulinum antitoxin stockpile further. We have also built our stockpile of countermeasures to address the effects of radiation exposure with products such as Prussian Blue and diethylenetriaminepentaacetate (DTPA). These countermeasures act to block uptake or remove radioactive elements such as cesium, thallium, or americium from the body after they are ingested or inhaled. Potassium iodide, a drug that can protect the thyroid from the harmful effects of radioactive iodine, is also in the Stockpile.

The Strategic Approach to Addressing Medical Countermeasure Gaps

The initial focus of our efforts to protect the Nation was aimed largely at those threats that could do the greatest harm to the greatest number of our citizens. Among biological threat agents, smallpox and anthrax are widely recognized as having the greatest potential to cause catastrophic harm. These Material Threat Determinations were among the initial ones made by the Secretary of Homeland Security. A sense of urgency has pervaded our efforts and we have defined new ways of doing business. Our new national security environment demands accelerated product development timelines and new paradigms of interactions between industry and government with increased risk-sharing and enhanced intra-governmental collaboration.

The focal point for USG interagency efforts to prioritize and coordinate medical countermeasures acquisition programs is the Weapons of Mass Destruction Medical Countermeasures (WMDMC) Subcommittee ("WMDMC Subcommittee"). HHS, along with representatives from the Department of Homeland Security (DHS) and the Department of Defense (DoD), co-chairs the WMDMC Subcommittee and stakeholders from throughout the USG are represented on it. Because HHS is the primary federal agency responsible for the development and acquisition of priority medical countermeasures, we have a major leadership role in the WMDMC Subcommittee.

The cornerstone of any sound acquisition program is the determination and prioritization of requirements and this is a primary activity of the WMDMC Subcommittee. In setting priorities for medical countermeasure acquisition under Project BioShield, the WMDMC Subcommittee considers a number of factors. The credibility and immediacy of the specific threats are driving factors and are informed by Material Threat Assessments (MTAs) conducted by the DHS. Acting Assistant Secretary Morr and Dr. John Vitko, here today representing DHS, will provide insight into these efforts. Other factors include an evaluation of the availability of appropriate countermeasures, both current and projected, and the target population for which the medical countermeasure would be used. In addition, logistical issues are considered such as the feasibility of deployment in a public health emergency, shelf life, and the storage and maintenance requirements. Project BioShield also requires a number of findings by the Secretaries of Homeland Security and HHS prior to an acquisition commencing. These findings include:

- Determination of material threat against the US population sufficient to affect national security. This determination is made by the Secretary of Homeland Security.
- Determination that countermeasures are necessary to protect public health. This determination is made by the Secretary of HHS.
- Determination of the appropriateness of funding acquisition of the countermeasure with the Special Reserve Fund (SRF). This determination is made by the Secretary of HHS.

Once these determinations are made, a joint recommendation for the acquisition is presented to the White House by the two Secretaries. If approved, Congress is notified and HHS executes the acquisition program.

The process that I have outlined for you has been successfully implemented three times since the enactment of Project BioShield less than one year ago. HHS has completed contract awards for acquisitions of the next-generation recombinant protective antigen (rPA) anthrax vaccine, the current-generation licensed anthrax vaccine (Anthrax Vaccine Adsorbed, AVA), and the pediatric formulation of potassium iodide. Additionally, the acquisition process is in the final execution phases for several other needed medical countermeasures including anthrax therapeutics, botulinum antitoxin, and a next-generation smallpox vaccine.

This robust interagency process mines the expertise of subject matter experts in the scientific and intelligence communities to define requirements for medical countermeasures and enable policy makers to identify and evaluate acquisition options to address immediate and future needs.

Application of the Strategic Approach: Anthrax.

The efficiency and effectiveness of the steps used to identify, prioritize, and acquire needed medical countermeasures is best exemplified by our efforts to protect the Nation in the event of an anthrax attack. It will also illustrate intra-agency and interagency processes.

Although anthrax is not transmissible from person-to-person, an attack involving the aerosol dissemination of anthrax spores, particularly in an urban setting, is considered by public health experts to have the potential to cause catastrophic damage. The potential for large-scale population exposure following aerosol release of anthrax spores, the threat demonstrated by the anthrax letters, and our knowledge that anthrax had been weaponized by state-actors, highlighted the nature of the threat. The Secretary of Homeland Security determined that anthrax presented a material threat against the United States population sufficient to affect national security. Because untreated inhalation anthrax is usually fatal, the Secretary of HHS identified anthrax as a significant threat to public health.

The approach to protect citizens against this threat demanded immediate, intermediate and long-term strategies and requirements. First, the existing stockpile of antibiotics in the Strategic National Stockpile was increased. Second, there is a need for a licensed vaccine to be used not only for pre-exposure protection for laboratory and other workers at known risk for anthrax, but for use along with antibiotics after an exposure, which could decrease the currently recommended 60-day course of antibiotic therapy.

Anthrax spores are stable in the environment and would have a profound impact if released in an urban population. Therefore, availability of a vaccine may be a critical requirement for repopulation and restoration of the functionality of any exposed area.

Due to limitations inherent in the currently available anthrax vaccine, there is consensus in the scientific community about the need to develop and acquire a next-generation anthrax vaccine using 21st century technologies. An assessment of developing technologies was undertaken by HHS experts in the fall of 2001 and the decision was made that there was a sufficient scientific foundation, including a detailed understanding of the pathogenesis of anthrax and how anthrax vaccines provide protective immunity, to support the aggressive development of a next generation vaccine consisting of recombinant protective antigen (rPA). The research undertaken to develop this vaccine, spanning more than a decade, was conducted in large part by the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, Maryland.

HHS defined a three-stage development and acquisition strategy with open competition for awards at each stage. The early and advanced development programs were supported by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) with contract awards in September 2002 and 2003, respectively. These were milestone-driven contracts with well-defined deliverables, including the manufacture of clinical-grade vaccine, the conduct of Phase I and Phase II clinical trials, and consistency lot manufacturing of vaccine. Large-scale manufacturing capacity would be required to support the civilian requirement for this medical countermeasure, which was defined by the WMD Subcommittee to be the initial protection of up to 25 million persons. Senior officials from several Departments of the USG evaluated acquisition options to achieve this requirement and, in the fall of 2003, approved the decision to pursue this acquisition of rPA anthrax vaccine.

An evaluation of the NIAID rPA anthrax vaccine development program indicated that it was robust enough to suggest that the rPA vaccine could become a licensed product within the statutory requirements. In March 2004, the acquisition program for this vaccine, under the direction of my office, was launched using the Special Reserve Fund created in the FY 2004 DHS appropriations bill. Utilizing a robust technical and business evaluation process, we reviewed multiple proposals and negotiated a contract for the acquisition of 75 million doses of the vaccine (anticipating a three-dose regimen). Using a milestone and deliverables approach similar to the ACAM2000 smallpox vaccine development and acquisition program, and the rPA anthrax vaccine development contracts at NIAID, the rPA vaccine BioShield acquisition contract lays out an ambitious program for the production of this vaccine. In accordance with Project BioShield, a critical aspect of this acquisition contract is the fact that no payment for product is made until a usable product is delivered to the SNS. While awaiting delivery of the rPA anthrax vaccine to the SNS, my office

awarded a contract last month for 5 million doses of the currently licensed AVA vaccine to support immediate requirements. Delivery of this product to the Stockpile began soon after contract award and over one million doses of the licensed anthrax vaccine are now in the SNS.

Application of the Strategic Approach: Other Medical Countermeasures

In an effort to fill other medical countermeasure gaps, we have made progress in contracting for products that are or will soon be delivered to the SNS.

Potassium Iodide.

In March 2005 a contract was awarded under Project BioShield for a pediatric liquid formulation of potassium iodide, a drug that helps limit risk of damage to the thyroid, from radioactive iodine. This formulation is aimed at young children who have difficulty taking pills and are at the highest risk of harmful effects from exposure to radioactive iodine. This acquisition will provide needed protection for at least 1.7 million children. Product delivery began in May and should be completed by the end of the fiscal year.

Ongoing Project BioShield activities.

In addition to the acquisition contracts that have been awarded since enactment of Project BioShield, there are several other important BioShield procurement-related activities underway. We are engaged in contract negotiations for anthrax therapies, and we are continuing to move forward on the acquisition of an antitoxin treatment for botulism. Furthermore, HHS has moved forward with the initial stages of an acquisition program for a next generation smallpox vaccine to meet a requirement for this product that addresses the millions of U.S. citizens who have contraindications for existing smallpox vaccines. A synopsis has been announced indicating that the RFP would be released later this month. This follows the consideration of industry comments received in response to a draft RFP that was released in May. We have also sought information from industry by releasing an RFI to assess the state of development of therapeutics for acute radiation syndrome.

Finally, in anticipation of yet to be determined requirements, we actively monitor the state of the medical countermeasure pipeline—both within and outside the government—by evaluating USG research and development portfolios and engaging industry through the publication of Requests for Information (RFIs). For example, we have recently released three RFIs to assess the timeline to maturity of medical countermeasures to treat nerve agent exposure, acute radiation syndrome, and additional products that might be available to treat anthrax. These requests are a key tool for HHS to dialogue with industry partners and to inform the development of sound USG acquisition strategies.

Priority Setting Beyond Smallpox and Anthrax

The approach taken to rapidly expand our Nation's response capacity to meet the medical and public health impact of either a smallpox or anthrax attack demonstrate our national resolve to address these threats. However, in many ways, anthrax and smallpox represent the "low hanging fruit" for medical countermeasure research, development and acquisition and was largely made possible by a substantial research base developed by USAMRIID and NIH. There was consensus that these were our highest priorities and we had countermeasures available or relatively far along in the development pipeline to permit acquisition. Given an almost endless list of potential threats with finite resources to address them, prioritization is essential to focus our efforts. We rely heavily upon our interagency partner, the Department of Homeland Security, to provide us with a prioritized list of threats along with material threat assessments that will include reasonable estimates of population exposure. This information is critical for future strategic decision making regarding how best to focus our National efforts in countermeasure development and acquisition, including whether in the short-term, the so-called "one-bug, one-drug" approach should continue while simultaneously investing in more broad-spectrum prevention and treatment approaches for the longer term.

Novel and Emerging Threats

The initial efforts for medical countermeasure development and acquisition have been rightfully focused on those threat agents known to have the potential to inflict catastrophic harm on our Nation. In addition, HHS and NIH are investing in efforts to address threat agents that we might face in the future, including engineered threats.

As is also the case for the known threat agents, we depend upon our colleagues at DHS to lead efforts to identify and prioritize these threats. One of the most recognized potential engineered threats is antibiotic-resistant anthrax, and the HHS, NIH and the U.S. Food and Drug Administration (FDA) accomplishments to date

in facilitating the development and acquisition of anthrax vaccines and therapeutic antitoxins have made an important impact on reducing our vulnerabilities in this area. In addition, NIH has made a robust investment in the development of novel antimicrobial agents and in addressing all aspects of antibiotic resistance. For example, investments have been made in the development of antibacterial agents that could potentially be useful against a broad spectrum of species and a wide range of drug resistance mechanisms. Finally, NIH is working with DoD to leverage medical countermeasure programs and resources of mutual interest.

Challenges to Rapidly Expanding the Strategic National Stockpile

Although defining priorities and quantifying the size of the threat to the population are the key steps in focusing our efforts, we must be mindful of the realities of the spectrum of efforts needed along the research and development pipeline to produce a useable medical countermeasure. The process of defining required specifications for a countermeasure often reveals few, if any, candidates in the pipeline. Basic research and early development efforts, even when robustly funded, often take years before a concept is mature enough for advanced development. The development of medical products—whether for cancer, influenza, or anthrax—is a complex, lengthy, and expensive process. Ultimate licensure, approval or clearance from FDA requires the rigorous accumulation of sufficient data in humans and animals to establish the safety and efficacy of the product for a specific use and the ability to consistently manufacture the product to meet the appropriate standards. It is important to note that a unique aspect of the pathway for medical countermeasures is the need to establish efficacy either using surrogate markers (such as the human immune response) or, using appropriate animal models, under the “Animal Rule” (Federal Register 67:37988–37998, 2002) because demonstration of efficacy against the actual diseases in humans is most often not feasible either because the disease does not occur naturally or for the obvious ethical reasons that prevent exposing humans to the threat agent. The USG is working to provide support for the developers of priority medical countermeasures through the research and development phases, and, when a product has reached the advanced development stage, Project BioShield provides an important incentive for manufacturers to take the product the rest of the way through the pipeline. And, as I have outlined here today, in the less than one year since Project BioShield was enacted, the incentive has expedited final development of several products for the Stockpile.

Conclusion

In closing, I must emphasize that the number of threat agents against which we could guard ourselves is endless and new and emerging threats introduced by nature or man will present continuing challenges. Although we cannot be prepared for every threat, we are implementing a strategic approach for identifying and combating the highest priority threats as assessed, in large part, by our colleagues from DHS, HHS and its agencies including NIH, CDC, and FDA, have a clear mandate from President Bush and Congress to lead the charge in responding to threat assessments and implementing sound development acquisition programs for priority medical countermeasures. We have already made important strides and will continue to work to address the obstacles identified. Mr. Chairman, I look forward to working with you and members of the Subcommittee to address the challenges of bioterrorism preparedness and its impact on public health.

I will be happy to answer any questions you may have.

Mr. KING. Ms. Morr, if IA information analysis has an assessment division with a staff of chemical, biological, radiological and nuclear experts, why is the S&T directorate the lead office for conducting BioShield assessments? Do you feel that IA is sufficiently involved in that process?

Ms. MORR. Yes, I would distinguish the two processes as IA putting into the threat process as we know it—that is our bread and butter—every day; and the material threat assessments in our view are really better characterized as risk assessments because they take into account consequences and some vulnerabilities and are pushing the high end of the venue. So, yes, we are—we feel that we are involved.

Mr. KING. Let me ask this question for the entire panel. As far as organizational issues between DHS and HHS and, you know, whether or not there is impediments to getting the job done,

wouldn't it be better for there to be only one process where DHS and HHS experts worked collaboratively to produce the best model assessment with respect to a given threat, rather than have it at two different junctures?

Mr. VITKO. I will start. Maybe Stew wants to follow up.

I think it could be done either way. I think the way it is structured now it falls into the natural domain. They are done collaboratively. HHS participates in the threat and risk assessments. We at DHS, in fact, participate in discussions around the medical countermeasure options and selections. It is just that we each have a natural expertise in an area and lead that portion. So by the assignment that is given it makes a clear responsibility for somebody to carry that action through and follow up on it.

Mr. SIMONSON. I agree with what Dr. Vitko said. It is done in a collaborative manner right now. The statute assigns very specific responsibility, as you know, to DHS for preparing the material threat determination. But we have tried through the short life of this program to do things in a collaborative way.

Mr. KING. Let me ask a more general question.

Based on the statement that Congressman Pascrell made at the opening of the hearing, that is a concern that we have generally, that we have Federal agencies now not talking to other departments, not talking to each other, not cooperating sufficiently. What can you tell us today here about the cooperation of HHS and DHS on this vital issue?

Mr. SIMONSON. I think there is an enormous level of cooperation among us. I think as the bill was being put together—this is one of the objectives in creating a joint institution essentially. The money is at DHS, the intel expertise is at DHS, the scientific public health expertise is at our place. So I think from the beginning it was intended to be a collaborative effort, joint institution. I think it has been getting better, and I think it is pretty good right now, frankly.

Mr. KING. Anyone else wish to comment?

Mr. VITKO. I would be happy to.

Mr. KING. This is an overriding issue overall, why I appreciate your comments on this.

Mr. VITKO. I think in this case we may be dealing with an exemplary process. Assistant Secretary Simonson said the legislation puts the responsibilities for that collaboration, but what is much more important is that collaboration exists in practice.

I cited the mechanisms that we talked about in my list of activities, both in our interagency bilateral and informal capacity. Those contacts actually occur several times per week. We know each other well. We exchange issues informally. We bring them up in formal ways. It doesn't mean we always agree. In fact, we sometimes bring different perspectives. But we interact regularly and work those through to a conclusion.

Ms. MORR. I guess I would just add to that in this business of Homeland Security and performing risk assessments is a spectrum in which each of us is representing our expertise and our customers. When we come together to provide those perspectives and niches, we come up with a better overall process, provided we keep moving with the process and not get hung up with unexpected

delays or inefficiencies. But when we each bring to the table our own constituents and our own expertise, we come out with a better full process along the whole risk assessment and response process.

Mr. KING. I yield.

Congressman PASCRELL.

Mr. PASCRELL. Thank you, Mr. Chairman.

I just wanted you to clarify, Mr. Simonson, page 1 of your testimony at the bottom of the page and continuing on page 2, you say that we have taken the botulinum antitoxin program started by the Department of Defense in the 1990s and we are now building our botulinum antitoxin stockpile further. We have also booked our stockpile of countermeasures, et cetera. Could you clarify that?

Mr. SIMONSON. Just, I think, as the first Gulf War was winding down

Mr. PASCRELL. I am sorry?

Mr. SIMONSON. As the first Gulf War was winding down, the Defense Department undertook a program to build a reserve of botulinum antitoxin. They had 100 horses or more lined up for this. They were vaccinated against botulinum, and then the process requires botulinum antitoxin to actually be introduced into them, and then they are bled. Plasma is collected.

They did all of that. But the next phase is to process it and turn it into a usable product. Well, they didn't do that. For a number of reasons that I am not familiar with, they decided to just put the stuff on ice, which they did.

When we learned that they had it, after 9/11, we sought to get a hold of it, get it transferred over to us, and then to finish it. In the meantime, the expertise to do this had largely faded in the country, and so we had to go out and get a new contractor to do it. That is what that refers to.

Mr. PASCRELL. So would you define very briefly what the stockpile looks like today?

Mr. SIMONSON. The numbers of doses?

Mr. PASCRELL. Give us an idea, relatively speaking, for those of us who aren't experts.

Mr. SIMONSON. We would prefer not to talk about the exact numbers publicly. I am happy to talk to you about it privately. We haven't divulged those numbers in public forum, as far as I can tell.

Mr. PASCRELL. Then we need to talk.

In fact, you know, my feeling is—I can only speak for myself—that the more not only we know but the more the public knows, they are put at ease. The less they know, the more difficult they have to come to grips with, God forbid, if something happens.

I would like to ask this question, and anybody who wants to respond. Well, let me ask you, Mr. Simonson, this next question.

Considering that DHS found that a pandemic influenza, if we ever had such an outbreak, can be as lethal or even more lethal than an anthrax attack, can you tell us where pandemic influenza ranks on your list of concerns in terms of preparations in the strategic national stockpile?

Mr. SIMONSON. I would say it is at the very top of our list of concerns. There is a program outside of BioShield that is designed to

develop countermeasures against influenza, and those programs are under way.

Mr. PASCRELL. Well, if we cannot combat the flu, how in God's name are we going to combat those other things that we associate with threats, biological threats? How do you do that? Tell me how to do that. Explain to the public how to do that.

Mr. SIMONSON. I am not sure I understand the question.

Mr. PASCRELL. We agree on my premise that this could be more dangerous—

Mr. SIMONSON. Absolutely.

Mr. PASCRELL. What are we doing about it?

Mr. SIMONSON. We have a program in—my office let a contract a while back to begin developing a new type of influenza vaccine, one that is not dependent on chicken eggs. That is how the current vaccine is made, in chicken eggs, not in biofermenters.

We are also in the process of looking for novel forms of administering the vaccine. Right now, it is one-shot 15 micrograms doses. The idea is to look and see if there are ways of conserving the antigen and using less material to produce an immunologic response. There is an enormous amount going on on this. I would be happy to give you a lot of details.

Mr. PASCRELL. We will be meeting, and you and I are going to be talking about anybody else who wants to be involved in the botulinum stockpile. That is a given, correct?

Mr. SIMONSON. Yes.

Mr. PASCRELL. My final question is this: We possess no vaccine to combat a pandemic influenza. How much has the Federal Government invested in stockpiling anti-virals that could be effective against a pandemic influenza? How much are you investing in this? We investing?

Mr. SIMONSON. Last year it was \$88 million. I don't have this year's number, but it is on that order of magnitude.

Mr. PASCRELL. That is sufficient?

Mr. SIMONSON. No, but the problem is that the industrial base supports only so much production. There is not a lot of this stuff out there.

Mr. PASCRELL. That is critical to what we are here about today—

Mr. SIMONSON. Yes.

Mr. PASCRELL. —in terms of the private sector.

Thank you, Mr. Chairman.

Mr. KING. Mr. Pascrell.

The chairman of the full committee, Mr. Cox.

Chairman COX. Thank you, Mr. Chairman, and thank you to our panel.

The BioShield statute requires that at the beginning of the process the Department of Homeland Security perform the role of determining what are the material threats, and they extend not only to biological but also to radiological and nuclear agents. As a result of the statutory procedure, the Department of Homeland Security has notified Congress of determinations made under the BioShield statute. I would ask, Dr. Vitko and Ms. Morr, how many times has that taken place?

Mr. VITKO. It is occurred four times. The material threat determination is done for four agents. It probably occurred in two sepa-

rate notifications. The first one was around anthrax, and then there was a subsequent one that made threat determinations around smallpox botulinum antitoxin and radiological nuclear devices.

Chairman COX. Once that determination is made, the Department of Health and Human Services takes over, if I am correct? Mr. Simonson, what then is the next step that you take, once that determination is sent to the Congress?

Mr. SIMONSON. We evaluate the public health consequences that inform the material threat assessment, make a determination if countermeasures are needed to combat those consequences. We do some modeling of our own as to the public health impact of the threat agent; and then, working with our colleagues at DHS, a unified recommendation goes forth to the President.

Chairman COX. Is all of this prior to the issuance of an RFP?

Mr. SIMONSON. Yes.

Chairman COX. What is necessary then for the RFP to be issued, finally?

Mr. SIMONSON. Once we have the approval from OMB to proceed, the development of the RFP goes forward, although we sometimes lean a little forward and start developing ahead of time. We publish a draft RFP to get comment back from the industry to insure that we haven't missed something or sent something out that is not tenable.

But it is a fairly elaborate process to produce an RFP that keeps open options to the proposer so that we don't get something back but then we have to throw out because there was some technical inconsistency with the RFP. So it takes some time, once the—

Chairman COX. To use an example, with anthrax, how long did it take from front to back from the assessment that was made at the Department of Homeland Security to the issuance of the BioShield RFP?

Mr. SIMONSON. We had the material threat determination—yes, we had the material threat determination in January of 2004; and the RFP was issued in March.

Chairman COX. Am I correct that in the anthrax case, which may not be an illustrative example for this reason, the threat determination was made first and the assessment was made second?

Mr. VITKO. Correct.

Chairman COX. That is not normal?

Mr. VITKO. That is not normal. That was done to jump-start the process.

Chairman COX. So let us say smallpox, using that as an example. I would like to include in this timeline the DHS and HHS pieces, if we can get our arms around that total length of time.

Mr. VITKO. A typical threat assessment takes 3 to 4 months to execute in its fullness, okay. That includes several sessions among interagency processes and to finalize the documentation.

We certainly have the information to help guide us in the process and be deliberated on the Weapons of Mass Destruction Medical Subcommittee before final completion of that document. So finally 2 to 3 months into that process we are able to start to the next steps.

Mr. SIMONSON. An RFP takes about 3 to 4 months from when we have the material threat determination to when we can launch the final RFP.

Chairman COX. Well, Mr. Chairman, I see my time has expired.

We are talking about time here and how much time it takes to get us even to the RFP stage, which, after all, is a request for a proposal. That is an intermediate step in the process itself. It seems to me that Congress needs to reconsider how this process works. What we really want to do is get the request out to industries so they know what to respond to.

What I am inferring from other comments that this committee has received is that, in many cases, people who might be interested in participating in these RFPs are complaining that the timeline for responding is so short that it seems to require that you have already got a product in the late stages of development in order to participate. What we really should be doing here is, in sending things that wouldn't otherwise be happening—I am not sure that the system that we have right now is serving that purpose.

But my time has expired, and I will come back with the next panel. Thank you very much, Mr. Chairman.

Mr. KING. I thank the chairman; and the gentleman from North Carolina, Mr. Etheridge.

Mr. ETHERIDGE. Thank you, Mr. Chairman.

Let me, Mr. Simonson, approach this a little different than the chairman did. From my understanding—and I would be interested in your comment on this—that the Nation's public health infrastructure, which is a place that we have if we are going to respond, is not ready to deliver the countermeasures even if they are successfully procured and stockpiled to HHS. What effort has the Department taken to prepare the public health infrastructure to respond?

I think it is critical. We haven't talked about that this morning. I would be interested in hearing any comment.

Mr. SIMONSON. There has been a fairly aggressive program since 2002 to build infrastructure in the public health sector. But you are quite right. We have a concern about localities being able to receive the stockpile and get it into the hands of people who need it within a very narrow window, and we are not quite there.

We have an initiative right now, the Cities Readiness Initiative, which is intended to really add some capacity there so that, combined with the other entities of the Federal Government, working with the local authorities, we can insure that we are able to get countermeasures.

This is especially true in the context of anthrax, countermeasures out and into people's hands within a 48-hour window. But there has been an enormous amount spent there. We have not quite seen the results we would like on building that distribution capability. Some jurisdictions have done a terrific job. But this is not uniform across the country, and we are working on that.

Mr. ETHERIDGE. Let me follow it up. Because the answer I got really isn't, to me, a good answer. You said, "aggressive, concerned initiative." I didn't hear anything about a plan with the results to follow up to make sure we have a measurement to know where we

are with follow-through in terms of having mileposts to know where we are.

Mr. SIMONSON. Well, that is the objective of the Cities Readiness Initiative, this program that we have to build capacity.

Mr. ETHERIDGE. Cities?

Mr. SIMONSON. Cities Readiness Initiative.

Mr. ETHERIDGE. For metropolitan areas?

Mr. SIMONSON. Yes.

Mr. ETHERIDGE. What about the rural areas?

Mr. SIMONSON. Well, at this point it is not in the rural areas. It is meant to be a threat-based metropolitan—

Mr. ETHERIDGE. You mean, we are not a United States of America?

Mr. SIMONSON. No, no, no, that is not what I meant at all. But there are varying levels of threats that we are working with, and so we are trying to reach out and to make strides there, strides which will be replicated across the country.

Mr. ETHERIDGE. I believe you need to work on your plan some more. Because—really and truly. Because we have seen, with what is happening in London recently and other places, they are looking for soft targets. Seems to me—I understand we have to have a high profile first, but we have got to prepare.

Let me ask each of the three of you this question, if I may. There are a number of States—my State of North Carolina included—has a large poultry industry. There is a large concern about the possibility of the spread of avian flu. Is DHS considering the use of the concern of avian flu as a similar disease? This could be a weapon of mass destruction as well. Have you done any work in this area at all?

Mr. VITKO. Yes. We have two activities. One is the risk assessment that I mentioned before in support of the President's Bio-defense for the 21st Century. Avian flu is one of the assessments considered in that risk assessment. The second is in the bioportfolio that I had. We had a special end-to-end study to look further at how avian flu would differ in a terrorist context than if it occurred naturally and what the synergisms could be for the public health sector in that.

Ms. MORR. I would say both the National Counterterrorism Center and IA have worked on a red cell product that looks at avian flu and tries to get ahead of actually seeing the threat. Dr. Vitko mentioned there will be a risk assessment done in January of a number of agents.

Mr. SIMONSON. I have nothing to add to that.

Mr. ETHERIDGE. Thank you, Mr. Chairman. I assume my time has expired.

Mr. KING. Thank you, Mr. Etheridge.

The vice chairman of the full committee, Mr. Weldon of Pennsylvania.

Mr. WELDON. I thank our distinguished witnesses for their testimony today.

Just to give some history to our colleagues on the committee, in October of 1997, as chairman of the Defense R&D Subcommittee, we had a hearing where Jessica Stern testified. She was, in her testimony, supporting the statement of Senator Richard Lugar that

in the 1993 attack on the World Trade Center the investigators and the sentencing judge both agreed that there was, in fact, a large cache of sodium cyanide that was actually in the Trade Center that was designed to be vaporized. But it wasn't vaporized. It, in fact, was burned. Had it been vaporized we would have had the first major attack of a chemical agent on our people that would have affected hundreds of thousands of individuals, from the first attack, not the second, the first attack on the Trade Center.

I am reminded of a hearing that Ken Alibek testified—again before my subcommittee in May of 1998. Dr. Ken Alibek, who is really Alibekov, who will be before this committee tomorrow—was in charge of the Soviet biological weapons program called Biopreparat before he defected in 1992. Ken Alibek testified back then that there were over 2,000 full-time Soviet scientists working on the weaponization of biological and chemical agents.

I won't go through all of the agents and the diseases, but it is significant. I have them all in front of me. I go through this because, as we go through the whole issue of biological warfare, it is a multi-pronged approach that we have to take.

It first of all starts with securing the current agencies stockpiles that are still occurring in Russia and the former Soviet states today. Our current effort while under President Bush has, I think, been improved dramatically, is still not adequate.

One of the things we are working on is an attempt to work with our industry—many in this room attended a session we had last evening—to try to work in a collaborative way with the Russian biological and chemical scientists.

After identifying and securing some 79 sites throughout Russia that have been identified, including six that we have never been into, the second part is to destroy those agents. That is also a massive project. Because if we don't secure and destroy them, then it is not that difficult for a terrorist organization or a rogue nation state to acquire the existing capability that was developed by those 2,000 Soviet scientists and researchers back in the Cold War.

The third major effort is to collaborate. That is where reaching out to our former enemies is critical. To that extent, we have been working for 2 years. Chairman Cox has been involved with this. In fact, he had 2-1/2 hour meeting with the counterpart, the chairman of the Duma Security Committee, General Vladamir Vassiliev, just a couple of months ago on establishing a joint effort that will give us access to those six sites in Russia that no foreigner has ever set foot on.

I mention all of this because I understand the importance of Bio-Shield II. In fact, that was the topic of our discussion last evening. But it is equally important, if not more important, that we deal with the storage and threats and perhaps the continued production or research on developing new strains that are still going on within the former Soviet states. It is a critical element that this committee needs to be questioned on, and tomorrow one of our subcommittees will do that when Dr. Alibek comes in.

We also need to focus on ways to encourage additional development of detection capabilities; and for that our military, our good friends at Aberdeen, our good friends at Ft. Detrick, are doing a

fantastic job in cooperation with our Homeland Security administration.

But, finally, and the subject of this hearing that is most critical, how do we encourage those private companies and small entrepreneurs to do research into strains that we have not yet provided proper support and protection against? That requires the passage of BioShield II, and it requires the input from the private sector.

What we encouraged last night in a continuing series of BioShield showcase workshops was a—basically an agenda that the private sector would bring to us of ideas, changes in our tax laws, our investment policies, so that private entrepreneurs and companies have more incentives to do the kind of work on these diseases that have been identified largely having been developed in the former Soviet States.

So I don't have any questions today. I challenge particularly the second panel to not just come and testify in this hearing today but to come in with a suggestion of ideas, a suggestion of policy options, legislative remedies and ideas that we can pursue in Congress to help have a more dramatic response to what we all know to be an obvious threat that has been documented many times over the past 10 or so years by a number of top experts, including Dr. Alibek.

I would again encourage our colleagues to attend that subcommittee hearing tomorrow where Dr. Alibek will come back and testify. He also wrote a book, Biohazard, which I would encourage everyone to read, which was published in 1998. This is a major threat to our security and one that deserves the full attention of our committee and the subcommittee.

Mr. KING. I thank the gentleman for his testimony.

The gentlelady from the Virgin Islands, Mrs. Christensen.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

I also want to begin with Assistant Secretary Simonson and follow up on the question of my colleague, Mr. Etheridge, because I really am not satisfied or clear about the answer. Because even as he said, even if we had all the countermeasures we need, which we don't, there is a great concern that the public health fracture is not there, and it really goes beyond even just the distribution capability.

So we are coming on 4 years post 9/11. I would like to know if the Department has determined a basic level of public health preparedness or readiness that every community should meet and assess the level of preparedness of public health around the country. Have you determined what level of funding is needed to bring it up to the state of readiness that it needs to be, and, if so, what is your timetable for

Mr. SIMONSON. Well, let me say that the cooperative agreements between CDC and HRSA to make these grants to State and in some cases is local units of government, they have outcome-based measurements and work is under way right now to evaluate those.

Mrs. CHRISTENSEN. In terms of those grants, I mean, how close do they come to what is really needed to prepare the public health?

Mr. SIMONSON. We are very comfortable with the cooperative agreement and the critical benchmarks that are in there and the outcomes that we have sought. There has been a fair amount of

money, you know. Since 2002, \$3.6 billion between CDC and HRSA have been sent out. We still have—I haven't checked the last few weeks—but we still had—nearly \$1 billion of that had not been drawn down. Some of that goes all the way back to 2002. So we think that the level of funding is adequate.

Mrs. CHRISTENSEN. Could you—Mr. Chairman, could we ask that the Department let us know where those funds have not been spent?

Mr. KING. Mr. Simonson, do you have any problem with that at all?

Mr. SIMONSON. Of course, I would be happy to provide.

Mrs. CHRISTENSEN. I would like to go on to another question.

Mr. KING. Provide to the subcommittee as well. I would obviously like to see that, as well as Mrs. Christensen.

Mrs. CHRISTENSEN. Thanks.

I have been—always been concerned about the dual responsibilities between the Department of Health and Human Services and Homeland Security, and we have talked about it insofar as different respects this morning. But in the event of a bioterrorism attack there is still some dual responsibility. How do you see it working? Who is ultimately in charge? Who is in charge?

Mr. SIMONSON. The Secretary of Homeland Security is the national incident manager in an event, whether it is a CBRN event or something else, some hurricane.

Mrs. CHRISTENSEN. We are talking about a bioterrorism event where we have to bring the public health modalities to bear and distribute from the stockpile and so forth. How does that work? How is that going to work? Who in the Department of Health and Human Services is in charge, at what level? Because you are not a public health—you don't have a public health background?

Mr. SIMONSON. No. The Secretary of Homeland Security is the national incident manager. He coordinates all the Federal Government's response. HHS has the lead for medical and public health response in a disaster, act of terrorism. In our Department, the Office of Public Health Emergency Preparedness is the coordinating entity among all of our public health service organizations that would respond to an emergency like that.

The CDC has the lead role as an operating division. That is what the CDC does. But, in addition to that, there are other elements of the Public Health Service, the Commission Corps, the National Institutes of Health. Recall back in—

Mrs. CHRISTENSEN. The Office of Emergency Preparedness has the top level of responsibility and the Department of Health and Human Services?

Mr. SIMONSON. The Office of Emergency Preparedness is the coordinating agency within the Office of the Secretary, yes.

Mrs. CHRISTENSEN. Let me ask another question, which any one of you could probably answer. But as we went through the BioShield hearings initially, I was one of the members here who was probably not very supportive of Project BioShield, or only reluctantly so. Reading the testimony of some of the companies that will talk—speak to us on the next panel, one of the issues is that the prohibition against utilizing some of these countermeasures in the commercial market is a big obstacle to us utilizing some of the

countermeasures that are available and could be used. As we look at BioShield II, what can we do about that prohibition against using it in the commercial market or some of the other issues? Or do you think that we should just scrap BioShield and use DARPA and the orphan drug process, which has proven to be effective in the past?

Mr. KING. Mrs. Christensen, your time has expired. I would ask the witnesses to answer. In about 15 minutes we are running up against some votes.

Mr. SIMONSON. Let us me answer as to scrapping. BioShield, no. DARPA—all the wonderful things DARPA has done it has not produced a lot of medical countermeasures, to my knowledge at least. There is no strict prohibition on the commercial market analysis. It is a consideration, when the Secretary makes a determination, but it is not a condition precedent. So it is not a strict prohibition.

Mr. KING. The gentleman from Pennsylvania, Mr. Dent.

Mr. DENT. Thank you, Mr. Chairman.

My questions are going to be directed to Dr. Vitko and Mr. Simonson. Are the Centers for Disease Control prevention list for category A, B and C pathogens insufficient or sufficient, number one. And, two, how does DHS take into account novel biological agents or biologically-engineered agents? How do you take that into account?

Mr. VITKO. I will answer both questions.

One is we believe the A, B, C lists—the category A, B and C lists are a good starting point but need to be expanded. One of the things we are looking at now, in fact, in doing the risk assessments for the Biodefense of the 21st Century is we are starting with that list, doing a fuller examination, doing a full analysis of the risks. I expect that we will validate most of the things on that list, but there may be some surprises that come up.

Second, with respect to how do we deal with novel and engineered threats, that actually is an issue that we worked with in HHS in developing a strategy. We did that over the course of 3 to 5 months—I don't remember exactly how many—in which we made our best collective assessment with intelligence inputs about what a terrorist might be able to accomplish in the way of engineering a drug in the next 3, 5 and 10 years, what indicators one would look for that might change our thinking, and then we developed a strategy based around that that had four key elements.

One was to do continuous technology watch and threat assessments to support that.

The second was to expand our biosurveillance and biodetection capabilities to look for unknown agents, not just a set that we are normally looking for on the suspect list, if you will.

The third was, in fact, to pursue additional medical countermeasures, and that might have broader applicability, but also very importantly to enhance the infrastructure for the R&D research development, test and evaluation of medical and countermeasures.

The fourth, very importantly and often overlooked, is to develop an integrated concept set of operations that says how would you respond to a new pathogen, whether it was for an emerging disease or an engineered threat. What are the steps in there so we could

get those worked out and then look at the places in there where we could reduce the timelines.

Those are the strategies we have been working on.

Mr. SIMONSON. I agree with Dr. Vitko's answer.

Mr. DENT. Thank you.

Next question, to date, the Department of Homeland Security has not completed a material threat assessment determination for a chemical agent. Why not, is the main question, and what would be your process for prioritizing those chemical agents?

Mr. VITKO. In fact, we have a draft material assessment written and in review on chemical nerve agents. It is still going through the vetting process, and this is a useful insight on all of these assessments.

As you might expect, there is little definitive information and a fair agree of uncertainty on a number of these issues. When we bring these issues together, we try to vet it extensively in the community. So we vet it from all perspectives and then reach a decision. We are still refining that process, that draft. We are probably a month away, is my guess, but I don't know that, actually, and I could give you a specific date when I call back.

Mr. DENT. Another question. I know the Federal Government this year will spend \$1.5 billion on BioShield—excuse me, we are spending \$1.5 billion of BioShield this year for vaccines on anthrax. For that cost, how many countermeasures will BioShield actually be able to purchase?

Mr. SIMONSON. It is a difficult question to answer. We haven't got the market research data, I think, to give you a precise answer. But we ought to be able—with the existing \$5.6 billion we ought to make major inroads in chemical, biological, radiological and nuclear threats.

I can't give you the exact number of agents that we are likely to have direct countermeasures against because, as I said, the process is ongoing. I have learned the hard way that you don't really know until after the proposal gets in. You know, you don't really know what it is going to cost.

Mr. DENT. Finally, last question. We could sit around here all day and think of the various frightening scenarios that could be launched against us. How will we know when we are done acquiring countermeasures, is my question. Is it based on how much we are willing to spend or, you know, what level of risk we are willing to accept? Or what countermeasures are not feasible or technically possible?

Ms. MORR. I would hope in this instance the threat would come in and play a big role—or at least in the initial guideline on what is the list of threats that we continue to see on an initial intelligence-based way to begin to inform whether we have adequate countermeasures.

Mr. SIMONSON. This may be a function of where I work every day, but it is hard to imagine a scenario where we will not be buying countermeasures or seeking to develop other countermeasures that have less of an adverse action profile, that are more efficacious, that cover a broader band of threats, to avoid the one-bug/one-drug concept. So I hope we will be developing those for years

to come. Whether or not we will stockpile them in enormous quantities as we do now is another matter.

Mr. KING. The gentlelady from California, Ms. Harman.

Ms. HARMAN. Thank you, Mr. Chairman; and I thank our witnesses. I think this is a very good hearing, and your comments and responses to questions are strategic. That is something, as I think everybody knows is critical if our Homeland Security effort and our counter bioterror effort are to succeed. It is not just rearranging the deck chairs. It is just creating one deck. As you have gone through the different pieces of an effective assessment and response, I think you are all focused on that. I want to commend you.

My question is about strategy and actions you are contemplating beyond U.S. borders. Germs don't recognize borders. This is obvious. I heard you discussing the avian flu. I am not sure if anyone mentioned SARS, but, you know, pick a germ, pick smallpox, pick anything. It should be obvious to all of us that if some evidence of that is somewhere else, given frequent travel in and out of America, that whatever is out there can come here easily.

So my question to the panel is, how do you think about intelligence on the existence of these bad germs in other countries, and how do you think about those germs coming here, and how do you think about the relationships that at least I think we need with foreign intelligence services, foreign health services, the World Health Organization and so forth with relation to this?

Maybe Ms. Morr is my candidate for response. I do want to commend her for an excellent report yesterday to the House Intelligence Committee on the London bombings.

Ms. MORR. Thank you.

On the intelligence side, the best mechanism that I believe we have in place right now is what I would call the red cell or alternative analysis piece of this. The community has done these estimates on SARS. They did it on the avian flu. It is the best way to sit down analysts and begin to talk about, you know, the threat and how it can evolve.

I think what the Department is learning how to do is you don't stop there. What is the next operational response that should be put in place and then what is the risk for the countermeasures? I think at that point, you know, we have got people at the borders, we have got other officials that we can, you know, declassify some of this information and make them more aware. But I think that what I see is, in the intelligence arena, I will call it a whole discipline of alternative analysis and thinking about how it can get to the shores is going to be really important as the OD&I sets up that whole new capability and gets us more focused on projecting out.

Ms. HARMAN. I would just add to that how it might leave us and go to other places. Let us not just think about America. Let us think about a world community, hopefully, which we hope not to harm ourselves by exporting some of these bad germs, am I right?

Ms. MORR. Absolutely. I would again say what is so unique about the Department is it doesn't stop, as you are talking about, with terrorism. It pushes the rest of the community to think about homeland threats in a much broader, you know, context. I think the whole community piece of putting the Department as part of

the OD&I and focusing on the international threats as you are talking about is really the wave of the future.

Ms. HARMAN. Thank you. Other comments?

Mr. SIMONSON. No, I agree with what Ms. Morr said. We are spending an enormous amount of time with respect to flu working with the World Health Organization and the impact capability to build a surveillance there. So I agree with you this is something we need to pay a whole lot of attention to.

Ms. HARMAN. Let me close with this, because I want to respect the time of others.

It is at our peril we build big walls around America and think that threats here are different or our only focus should be or can be on threats here. There is one world here, and in an era of terror we better get it right across the world. I think ultimately it is the only way we will win against the threats of the 21st century.

Thank you, Mr. Chairman.

Mr. KING. Timing is everything.

The gentleman from New Mexico, Mr. Pearce.

Mr. PEARCE. Thank you, Mr. Chairman.

My first question I think would be for Ms. Morr. It may have been asked, I apologize, if we have enough intelligence to determine the capability and intent, I think that was your testimony, do we have enough capability to stop it rather than provide a response?

Mr. SIMONSON. I am sorry, I didn't understand.

Mr. PEARCE. Why don't we remove the intent and capability, rather than trying to inoculate against every response they can do to us?

Ms. MORR. The issue of the capability is that we don't have all of the factors to make a definitive conclusion on capability. What we do have is a steady progression of learning and at some point—for example, we took down some of the training camps. It is not—the people that have that capability, that kind of expertise are still around. They are easily acquired throughout the world. It is never something that you can automatically definitively eradicate. A lot of this is a skill set that exists in people, in training, and available in stockpiles or skill sets around the world. So the capability—

Mr. PEARCE. I use those skill sets to obtain and pass along. Because if we know who the individuals are who would create smallpox, it seems like it would be easier to eliminate them rather than spend billions that may not be spent in the proper fashion.

You don't have to address that.

Mr. Vitko, how complex is it to develop and maintain strands of smallpox and anthrax, for example? How difficult is it for the terrorists to maintain their ongoing supply stock?

Mr. VITKO. Let us say that with anthrax it is quite feasible. I could give you more specifics in a closed session.

Mr. PEARCE. It is quite easy for them to develop and maintain, in other words—in other words, the vaccine has run out of date. Do the diseases that are being created kind of fade if they don't put them into actual act, if they don't put them into functioning?

Mr. VITKO. I am missing part of your question. I thought the original question was around the technical feasibility of a terrorist developing an anthrax—

Mr. PEARCE. No, maintaining it if they develop it. Do they have to maintain it or, once it is developed, and it is a formulation in your mind, or do they then have to develop a sample and culture and maintain?

Mr. VITKO. In the case of anthrax, it is a hardy agent.

Mr. PEARCE. It is straightforward and stays there. How easy is it to develop new strands that are resistant to our counter-measures?

Mr. VITKO. The other issues, what do you lose when you develop those strands? Any kind of genetic engineering comes at a cost in an organism and details. Again, because of the sensitivity, I would prefer to discuss it in a closed session.

Mr. PEARCE. Same thing on smallpox. My fear is we are going to put—I mean, we have \$5.18 billion I think that is targeted, basically 2 on a list of 52 possible threats, and so you begin to genetically add on top of that. I am not sure we are going to add \$250 billion. But even if we do, as we develop the remedy, they develop things that are resistant to the remedy—and you are shaking your head no. Is that not possible?

Mr. VITKO. I hope I wasn't shaking my head no.

Mr. PEARCE. It was a little quiver.

Mr. VITKO. No, no. What I would say is that I understand your concerns and your extrapolation and just multiplying that. I would say that the threats that we have currently addressed—anthrax, smallpox and botulinum—are the highest threats on the list. So taking that and simply multiplying and saying if I have 20 agents I have to do 6.5 times that—

Mr. PEARCE. Fair enough.

Trying to get my last question in, Mr. Simonson, what is the life of the smallpox vaccine that we currently have in stock? You said we have enough stock to handle all of our citizens. At what point does that become—

Mr. SIMONSON. What is the shelf life?

Mr. PEARCE. Yes.

Mr. SIMONSON. The sizable amount of our stockpile has been around for a long time and is still very potent. So we are hopeful that the new material that we are making will have a very long shelf life.

Mr. PEARCE. Thank you, Mr. Chairman.

Mr. KING. The gentleman from Connecticut, the chairman of the Subcommittee on Intelligence, Information Sharing and Terrorism Risk Assessment, Mr. Simmons.

Mr. SIMMONS. Thank you, Mr. Chairman; and I thank the witnesses for their testimony.

I wanted to focus on Ms. Morr's testimony, although others may wish to respond. I am recalling one of my favorite movies, *Casablanca*, with Humphrey Bogart and Peter Lorre where the phrase "round up the usual suspects" occurs at least once. In looking at what we have done to deal with the threat of bioterrorism, by communicating with the National Counterterrorism Center, CIA, FBI, the various BKC entities, the labs and so on, I think you have done a good job of rounding up the usual suspects.

My question goes to this, however. Are we also thinking out of the box? Are we making substantial initiatives with academia—and

traditionally the intelligence community and academia have had somewhat of a difficult relationship. Are we talking full advantage of information that is available in the open-source domain, and are we trying to solve some of these problems in nontraditional ways because we are dealing with a nontraditional threat? That would be my first question.

My second question, are we moving fast enough? I think we have one MTA completed, two MTDs, others in the process. Are you satisfied with the speed with which we are moving on some of these programs?

Then the final question is, are we getting the word out to our State, local and tribal partners? I know that you are having briefings. I would be interested to know where and how frequently those briefings are taking place. Perhaps—certainly myself, but perhaps members of the committee would like to attend a regional briefing, just to see how that goes. So three questions.

Ms. MORR. Let me start with the last one—

Mr. SIMMONS. Out of the box, fast enough briefings.

Ms. MORR. Let me start the last one first. The briefings are being done, I would say, rather ad hoc on a—as we go out, we know we are going to be there, or there is a request. And so we need to beef that up, and we plan to do a more thorough outreach program.

I would also say that I think we have done a much better job of getting those information bulletins out to State and locals. We have done a couple on like when the financial institution surveillance came up, the HVAC systems on the top of those buildings, put out a State and local information bulletin on making sure those were looked at as protective measures because they could be used as dispersal devices for chemical, biological weapons.

On the are we pushing the envelope, we frankly rely an awful lot on S and T to help us with pushing the envelope. They have the types of expertise to bring us together to get in a room and push the envelope. Quite frankly, we are just trying to keep up with a lot of the basics.

I will go back again to my remarks to Congressman Harman that the DNI now is going to take on a whole lot more responsibility when we do these interagency threat assessments. There will be a piece on the end of this that sort of pushes the envelope on the what if scenario. The sector assessments that we were beginning to do out of DHS, the first one will be the chemical sector. These are requirements to the private sector. They will also have the what if factor to it. So there is a number of mechanisms in place.

And the middle question was?

Mr. SIMMONS. Out of the box.

Ms. MORR. Out of the box. I would go back to our colleagues here back in S and T. We depend an awful lot for them to bring us together and do out of the box. We have had a couple briefings from people in the community that have come and told us about the complex urban environment, how all of this hooks together. So we are very much aware of it, just have not had the capability to deal with it in a multidisciplinary fashion yet.

Mr. SIMMONS. I thank you for those remarks. I will simply say I think you know I am an advocate for open source intelligence. I think it really applies to the Department of Homeland Security,

and I think we can build a robust capability in that area that works to answer many of these questions in an open and transparent way, which I think is really important.

With regard to your regional briefings, if you are coming to the New England area, I would be happy to attend. I am sure my colleagues would be happy to attend briefings in New York, New Jersey, and elsewhere.

Thank you, Mr. Chairman. I yield back.

Mr. KING. I thank the gentleman for injecting Hollywood into an otherwise very somber hearing.

The gentleman from Texas, speaking of Hollywood, Mr. McCaul.

Mr. McCAUL. Thank you, Mr. Chairman. I am reading the book 1776 by David McCullough. I will go to a literary piece, if that is all right. It is interesting, General Washington, as the Revolutionary War is starting, talks about the weapon of choice by the British, and he talks about smallpox, how the British were trying to infect our troops with the virus. And so this is not a new, a brand-new idea. We had our Homeland Security retreat where we talked about an epidemic; had a tabletop exercise, an outbreak of smallpox globally start in Europe, and the question was, what do we do? Do we send some of our stockpiles over to Europe to build a ring around there?

And my question is, I know we have enough stockpiles in this country for our own citizens, but in the event of an outbreak in Europe where we want to send the vaccine over to Europe to prevent the spread, the issue came up, and this may be a very simple short answer—the issue came up with respect to dilution. If we can, if it is scientifically possible to dilute the vaccine by a ratio of 2 or maybe 4 to 1 and the vaccine still be effective.

Mr. SIMONSON. There is research over at the National Institutes of Health done right after 9/11 that indicates that a 5 to 1 dilution still produces a good immunological boost. The license isn't for 5 to 1, so it is a little—there is some technical issues that we have to deal with, but it can be diluted. Now, we don't know, I think, about the new material; I don't believe those studies have gone forward on the newly produced vaccine.

I should also say that there is—WHO, World Health Organization, manages a virtual stockpile of about 30 million doses of smallpox. It is 30 million, isn't it? About 30 million doses of smallpox vaccine. And they are building more. Yeah. So just—

Mr. McCAUL. So we have an adequate supply; and the answer is, yes, we can dilute, if necessary, to stop the spread overseas as well, I guess, right?

Mr. SIMONSON. I am sorry, I was just checking.

Mr. McCAUL. That is okay. I guess the answer is we have an adequate supply here; but we could also dilute, if necessary, to prevent the spread overseas?

Mr. SIMONSON. Yes. And, in fact, we participate in and we are able to participate in the WHO virtual stockpile because of this ability to dilute here originally. Now we have more product one for one that we can use. WHO, their objective is to be at around 150 million doses in this virtual stockpile, but I don't think they are much higher than 30—right now.

Mr. MCCAUL. My second question has to do with security of the biological agents in existence, both in the—you know, when the former Soviet Republics had this intense biological warfare center going, we stopped our program in the Nixon administration, obviously Fort Detrick, we have CDC, we have a lot of level four facilities in this country. I had a tour of the Southwest Research Lab in San Antonio, some pretty nasty viruses that they have there. And my question is, what are we doing overseas particularly in Russia to secure these agents, but also what are we doing at home to better secure the biological agents we have in this country? Because when I got the tour, I have to tell you, I was a little surprised at what I noticed to be a lack of security at that facility.

Mr. SIMONSON. I can answer the domestic part of your question. The CDC runs the select agent program, which requires very specific security handling of the most dangerous of these agents, control in the way they are handled in the lab and also in the way they are shipped, background checks for people who use them and that sort of thing. It is, we think, an effective program.

But our experience in securing this sort of material is only a few years old; and, indeed, when Secretary Thompson directed Public Health Service agencies to take much more aggressive steps to secure material, there was a fair amount of resistance because it just is counter to the culture in some of these labs.

I am happy to say that they have all come along very well, and we are very happy with the level of security improvements. But the select agent rule is our principal mechanism for controlling these things domestically.

Mr. MCCAUL. I am glad to hear that.

What about—can anybody comment on securing agents in Russia?

Mr. VITKO. That generally falls under the domain of the Department of Defense and the Cooperative Threat Reduction Program.

Mr. MCCAUL. Okay. Lastly—

Mr. KING. The gentleman's time has expired.

Mr. MCCAUL. I will pick it up next time.

Mr. KING. Okay. The gentlelady from New York, my colleague, Mrs. Lowey.

Mrs. LOWEY. Thank you. And I want to thank the Chairman, and I apologize having to go to another event in between.

But I would like to follow up, Mr. Simonson, on your responses to Mr. Pascrell's questions, because one of the things that has concerned me as a New Yorker since 9/11, 3 years later we are still not coordinating between the agencies. Now, the center, as you probably know, the Infectious Disease Society of America, recommended that the Federal Government stockpile vaccines and antivirals in advance of a pandemic influenza outbreak. They recommend a stockpile to cover 50 percent of the population. In the United States we have a stockpile of less than 2 percent; England has a stockpile of 25 percent; France has a stockpile of 20 percent; and Canada for about 17 percent of its population.

Now, what concerned me when my colleague Congressman Pascrell asked you the question, you didn't have a response. So maybe you are not as worried about avian flu and other infectious diseases as I am. But when Julie Gerberding appeared before my

committee, Labor, Health and Human Services, Education Appropriations Committee, they clearly didn't have a plan to get from 1 percent of Tamiflu antivirals up to even close to what England has, what France has, what Canada has. Can you explain this? I don't get it.

And I would like to know, if a pandemic arrived on the U.S. shores tomorrow, has any progress been made to cover the population? Is the CDC working with other agencies in the Federal Government to build up an antiviral stockpile comparable to countries like England, France, and Canada? And do you agree with the 50 percent?

In other words, what are you doing? Why aren't we making progress? And why can't you respond to my colleague Congressman Pascrell, who is asking a question that I think every American wants an answer to?

And I feel a real sense of responsibility to know why we are not moving faster. We have to, it seems to me, have comprehensive plans, we have to move fast, and we have to have plans in place and then fund them to do this. How much money do you need? Why isn't it moving? Give us a number, and let us get it done.

Mr. SIMONSON. Well, thank you, Mrs. Lowey. I thought I had responded to the Congressman's question, so if I hadn't, I appreciate the opportunity to try again.

We have now a stockpile of antivirals. It is not what the U.K. has ordered; however, it surpasses—

Mrs. LOWEY. What percentage of the population would it cover?

Mr. SIMONSON. I think you are about right there.

Mrs. LOWEY. So we are at under 2 percent compared to the U.K., compared to France.

Mr. SIMONSON. Well, actually the U.K. doesn't have all of theirs yet. I mean, we have probably surpassed them right now. It will take them some time to build up. We started building this up a while back.

The industrial base to make this stuff does not exist to immediately or even in the intermediate term get up to the numbers that you are talking about, 50 million.

Mrs. LOWEY. And forgive me if I am interrupting you, but I know the gavel is going to come down in 5 minutes. We know that it would take \$100 million and a year to build another factory. We had the experience with Chiron; we lost 50 percent—correct?—of our vaccine. And this was just for a regular flu. Why can't we do it? Here we are, the richest country of the world, why can't we do it? How much would it cost? How long would it take?

Mr. SIMONSON. As to Tamiflu, as to that antiviral, the active pharmaceutical ingredient comes from Asia, comes from a plant. That is the limiting major factor.

Mrs. LOWEY. Can we make it here?

Mr. SIMONSON. These are discussions that are occurring.

Mrs. LOWEY. Three years after 9/11, and we are still having the discussions? Why can't we do it?

Mr. SIMONSON. We have also invested, as I indicated earlier, in technologies to convert over and to be able to surge our vaccine capability. This is the so-called cell culture or tissue culture vaccine, entered into a contract some months ago on that. We have taken

steps to secure the egg supply that is used for the current vaccine. They are subject to avian disease and so forth. And also, we have taken steps to be able to surge production of these eggs so that if we needed to vastly expand the amount of vaccine we produce, we can do that.

Unlike the U.K., we have gone in and produced commercial runs of H5 and 1 vaccine. And we have H5 and 1. This is the avian strain floating around Asia right now. We have clinical tests under way right now to determine how that vaccine can be used.

So there is a fair amount of activity here, and there is no threat that we take higher than pandemic influenza. We came forward in our 2003 budget request for 100 million to build the Nation's pandemic influenza preparedness, and that is what helped us do some of these things in terms of securing the egg supply and building a cell culture base. But it takes some time. There is no way we will be able to get up to these levels of coverage, 50 percent, that the IDSA is recommending. And even if we did, there is a very serious debate in the public health community about the wisdom of that.

This is a very expensive drug. When you, as Dr. Gerberding has said—when you use these things, you lose them, because the virus mutates, it develops resistance. And so what we are focusing on is much more of a vaccine-driven approach.

Mrs. LOWEY. Let me just say this in conclusion. I understand, based upon information from the CDC and Dr. Gerberding, that they are working on a vaccine, and at a minimum it is going to take 6 months to get this vaccine produced; isn't that correct?

Mr. SIMONSON. We already have some.

Mrs. LOWEY. It is still mutating. We don't really know. But if, God forbid, that avian flu began aggressively mutating to humans, what I don't understand—and I asked this of Dr. Gerberding, and I have great respect for her and Dr. Fauci. What I don't understand is when the military needs a weapon, we produce it and we stockpile it. And if—and I understand if you don't need it, please, God, we won't need it, you may have to throw it out. So be it. They throw out weapons, too.

I don't understand why we are at 1 percent, England is at 25 percent, France is at 20 percent, and Canada is 70 percent. With all the people we have working on this, there seems to be a lack of determination and a lack of focus. And ask us for the money. I mean, ask us for the money. Why are we still depending on one factory? And why are we still depending on an overseas supply? Last time it was London; now it is Zurich.

I think we have real problems here, and I would like to see a sense of urgency. And, again, if the vaccine goes bad because we don't have it, so be it. It is like an insurance policy for the American people. And, to me, it is really disappointing that we can't tell the American people that if, God forbid, something happened, we are ready.

Mr. SIMONSON. As much as I admire and respect you, Mrs. Lowey, I have to disagree. There is a very serious determination at our Department to address influenza. We took very proactive steps long before there was interest in the general population and indeed some quarters up here on influenza. We were very aggressive.

Mrs. LOWEY. If you are so aggressive, then why do we still have one factory.

Mr. KING. We will let Secretary Simonson answer, then

Mrs. LOWEY. Okay.

Mr. SIMONSON. They are the developers of this drug. They are the ones who own the drug. That is the way it works.

Mrs. LOWEY. This is a longer discussion, and my time is up. And I am rooting for you, and I do hope that we can resolve it because the health of the public is at stake.

Mr. KING. We have just seen a match made in heaven. The gentleman from the State of Washington, Sheriff Reichert.

Mr. REICHERT. Thank you, Mr. Chairman.

We are all rooting for you. The whole country is rooting for you. You have a tough job, and we know that. Some people might think it is a disadvantage to be one of the last people to ask a question; those of us who are freshmen Congress Members, House of Representatives Members, are usually left to last. But we kind of get the opportunity to sum up just a little bit, too.

My background is in law enforcement, as the Chairman mentioned the word "sheriff." I was the sheriff in Seattle for 8 years, and 33 years in law enforcement. So what I have heard—and I just jot down a few words that all three of you have spoken since I have been here this morning. I really am encouraged when you use words like technology and research and development and intelligence gathering and assessment, risk assessment, and the sharing of that intelligence, and State and local bulletins. Those are important words for local law enforcement across the country to hear. They understand those words. Partnership is huge, outcome-based, all of those terminologies. And most of all, I think most important is someone used a little bit earlier integrated operation. And this is the tough place to get to, and we understand that in the local law enforcement world.

I am also glad to hear that you have a structure set up where you have an incident manager, and then you have listed HHS and CDC and the Office of Public Health and Commission Corps and all of those entities that come under the direction of the incident manager.

I understand incident management very well, having been a SWAT commander for years, but there was some concern and always has been about information that comes to or doesn't come to local law enforcement, especially in light of the recent events in London and the inability of local law enforcement in the northwest part of the country and not hearing about this until hours and hours later, and then having to take action in a Metrobus tunnel or on a train that might run through the city of Seattle and the county that I live in.

My question is you have mentioned all these other entities, but I haven't heard really any talk about how you might be interacting with local law enforcement and what you see their role in the whole BioShield Project, because I know that we have a role to play in this event. Public health has got the majority of the shouldering the burden here, but what do you see as the role of local law enforcement agencies in this effort?

Ms. MORR. As I mentioned before, on the bulletins, one of the reasons that we do put out information bulletins, the whole reason is to inform people of what to look for, because what we are trying to do is encourage the reporting both locally through the JTTFs and on through the Department of Homeland Security. And as we begin to set up these fusion centers, not we, the Department, but as the State and local jurisdictions to begin set up their fusion centers, it is important that we have a reporting mechanism.

As you may know, we have the Homeland Security information networks. Seattle is a robust member of that network. It has interoperability with RISNET and LEO, and so we are continually mining the information that is passed to us, and that is where we post the information and the analysis that we do. So we do believe we are on the cusp of this more active information exchange, not just through paper or faxes or e-mails, but also through the interact that the HSIN provides us.

In terms of local law enforcement, the ones that I have talked to, I mean, they have been so proactive of reporting incidents that they do see. You may know of our Terrorist Screening Center, for example. This isn't the biothreat, but it is the same mechanism. These officers are out there sending in people that they are stopping, and we are getting hits on criminals or in some cases people in our terrorist databases.

So I think it is a revolution in the way that we are reporting information and sharing information. And I see that the same way as BioShield. It is going to be the officers on the job who notice that there is, you know, funny lab equipment being stockpiled in an apartment building that they may go into, or noticing that a student is communicating at an Internet cafe with several others and wants to report on that that activity. So I think it is the continued spectrum of it is going to happen locally. We need to prepare our eyes and ears on the ground.

Mr. REICHERT. I appreciate that.

I see my time has expired, Mr. Chairman. Thank you.

Mr. KING. Thank you, Sheriff Reichert.

And the gentleman from Washington, Mr. Dicks.

Mr. DICKS. I know this subject has been discussed, but I would like to go back to it. What are we doing with the public health infrastructure? I am told that if we had this, a nuclear attack, for example, and you got into advanced radiation syndrome, that, in fact, we are going to ship people to other parts of the country by rail or train or some other way? Bus? I mean, are we doing enough in New York, Washington, and the major cities to have public health people who can deal with these victims of an attack? Let us say we had a nuclear detonation. Our friend Curt Weldon talks about it. We lose a million people. But a lot of them would be the people who don't die but are affected by the radiation. What are we doing on that score?

Mr. SIMONSON. We have made—as I said a bit earlier, we have made very substantial investments since 2002 in our public health infrastructure, about 5.2 billion between our HRSA grants and CDC grants. One of the programs that HRSA funds is a surge capacity program in order to build additional capacity within existing hospitals to handle local events.

But an event, Mr. Dicks, like the one you referenced, is not something that is going to be able to be handled in a local part of the country or even in a region. We are going to have to move people out; we are going to have to bring assets in. A good example of this is the burn capacity in the Nation, burn hospitals. We have a fairly modest burn capacity in this country, probably no more than 2,000 licensed burn beds across the whole country. And so one of the things that we are doing is working with the Burn Association and trying to figure out alternate ways to be able to absorb large numbers of burn patients.

Mr. DICKS. You mentioned two sources of funding HRSA and CDC. Have they been increased, or are these the same budget levels that we had prior to 2001?

Mr. SIMONSON. They have not been increased. There is a—

Mr. DICKS. Yeah. I mean, it is the same amount of money that we have been using; now we are just using it for these additional problems. Isn't that correct?

Mr. SIMONSON. Well, and it is not entirely expended. As I said, we have monies still from 2002 that have not been drawn down. And so it is not clear that more money—

Mr. DICKS. We are on the Appropriations Committee; we can take care of that. Why hasn't it been spent?

Mr. SIMONSON. This is a question for the authority receiving it. It is within their power to do that. But I can tell you, from fiscal year 2002 grants—now, this is an older run. It is good as of June 14th—we have something like 92 million that has still not been drawn down.

Mr. DICKS. Out of 5 billion? Or how many billion was it? I assume you are talking about the HRSA money.

Mr. SIMONSON. That would have been—it is about 10 percent of the 2002 money that was not drawn down.

Mr. DICKS. Is this HHS's fault, or has it been granted?

Mr. SIMONSON. It is granted. It is out there. It is just a question of—

Mr. DICKS. It just hasn't been spent.

Mr. SIMONSON. Right. So as I said, it is not clear to us—

Mr. DICKS. Can you give us a list of who hasn't spent the money?

Mr. SIMONSON. Yeah. Your colleague requested, and I will be happy to provide that.

Mr. DICKS. Thank you, Mr. Chairman.

Mr. KING. Thank you, Mr. Dicks.

I want to thank all members of the panel for your testimony today, for your patience, and for your perspectives. And, with that, the panel is excused.

Mr. KING. I would ask the second panel to step forward. Thank you very much.

I want to thank the members of the panel for taking the time to be with us today and for your patience in sitting through the first panel. We will start and try to move this along. We do have votes coming up at approximately 12:00. At most it will be a brief recess; we will keep the hearing going until everyone has had a chance to both testify and answer questions from each member of the committee.

I will recognize Dr. Marcus Eugene Carr, the executive director for clinical research-hemostasis, at Novo Nordisk, Inc., to testify.

STATEMENT OF MARCUS EUGENE CARR, JR.

Dr. CARR. Thank you, Mr. Chairman and members of the subcommittee. I appreciate the invitation to appear on behalf of Novo Nordisk today. I am Mark Carr. A little bit of background. I am an executive director for clinical research in hemostasis at Novo Nordisk. Hemostasis is blood clotting, and I have been involved with business development and regulatory approval for a primary product known as NovoSeven. I have got extensive experience in real-world treatment of acute bleeding and mass casualties, with over 3,000 hours as an emergency room physician; I have been a professor of medicine in pathology at the Medical College of Virginia in Richmond; and I am currently a colonel in the Medical Corps of the Army, having served in Desert Storm, Desert Shield, Noble Eagle, Enduring Freedom, and the Kosovo campaign.

Novo Nordisk is the world leader in diabetes care, and with the development of NovoSeven introduction has taken a leading position in the treatment of bleeding disorders; also produces growth hormone and hormone replacement therapies. At U.S. bases in Princeton, it has greater than 20,000 full-time employees in 78 countries. And so it is truly a global organization, and produces products and markets them in the United States and 180 other countries, and is traded on the New York Stock Exchange, London, and Copenhagen Exchanges.

But Novo Nordisk is not a biodefense company, and it does not have as its primary focus the Federal market as a marketplace. However, we will work diligently to supply medications that the Federal Government identifies as critical, and since 9/11 we at Novo Nordisk are becoming more and more convinced that NovoSeven is such an agent.

There has already been several discussions about the chemical, biological, and nuclear threat. One of the problems with it is the similarity of symptoms that some of these agents produce can look as simple as a cold, developing into a rash and a fever, and then end with massive bleeding disorders. Because of that, in many instances, probably the first indication of a bioterrorist attack may be previously healthy people who develop similar symptoms and are known to have a common site of exposure. Therefore, it will be difficult to get a rapid specific diagnosis, and, therefore, early treatment in lots of cases will be simply symptomatic: Treat what the patients appear to be presenting to you.

Strategies for preparations for such an attack does include preventative, such as vaccines, but also the development of countermeasures for postexposure, and to this point, this has primarily been antibiotics. But I would point out there are no approved therapies for hemorrhagic fever viruses, and therefore initial treatment will once again be symptomatic.

There are problems with countermeasures, and these include—most to this point have been targeted to specific agents, and therefore very few are fully developed, Cipro for anthrax being probably the only one. Many are at very early stages of development. There is also a very critical window in which they can be applied. If you

give them too early or you give them too late, they simply don't work. There is also a period of latency which makes it even more complex, and you can end with a dead man walking syndrome where they are not effective.

Therefore, countermeasures that are broadly applicable to the symptoms of the patient will be needed. NovoSeven may be one of those measures. It is a mature medical product, having been used for treatment of bleeding for more than 10 years. It has a unique mechanism of action, stops bleeding that is refractory to all other forms of therapy. It works at the site of injury, and therefore side effects are reduced. And we think that it might be an agent where we can extend the window of opportunity where you could have more time to diagnose a patient and treat specifically with the agents under development.

NovoSeven reached the market in 1996, has been given more than 700,000 doses. It is 90 percent effective in the worst of bleeders, which is hemophilia, and has reported uses from the literature in multiple other indications. It is a recombinant product, it is safe; there are no human proteins. It undergoes a dramatic purification process, no viral contamination. It is nonantigenic. Its main potential side effect would be thrombosis production, but that has occurred in 104 out of 700,000 doses.

So why NovoSeven for Project BioShield? First, Novo Nordisk, the company producing it, is a qualified health company. Inclusion of NovoSeven would send a positive signal to equally qualified companies. NovoSeven is FDA-approved, it is available, it has a broad spectrum of activity, and may be of use in things like hemorrhagic fever viruses or end stage bleeding from multiple causes. I would also point out that it has potential in trauma; and as recent events in London have demonstrated, explosive devices remain our enemy's weapon of choice.

We do have a couple of proposals for improvements in the BioShield process. The current scheme—

Mr. KING. Excuse me, Dr. Carr. I would ask you to try, each of the witnesses, to keep this to 5 minutes, because we do have a series of votes coming up at 12:00, and to try to get everyone at least to make opening statements before we go for the votes, and then come back for the questions. So if you could try to wrap up, I would appreciate it.

Mr. CARR. The recommendation I was going to make is that BioShield consider simultaneous stockpiling of vaccines and therapeutics, and also encourage pharmaceutical companies to look at their products for potential uses in the BioShield area. This would maximize near-term solutions.

And I thank you for your attention. I will stop there.

Mr. KING. Thank you, Doctor. I am sorry for the interruption.

[The statement of Dr. Carr follows:]

PREPARED STATEMENT OF MARCUS EUGENE CARR, JR., M.D., PH.D.

Mr. Chairman, members of the Subcommittee, thank you for the invitation to appear before you today on behalf of Novo Nordisk. I am Marcus Carr, Executive Director for Clinical Research-Hemostasis of Novo Nordisk. I am here today to give you information and perspective about the use of Novo Nordisk's drug NovoSeven® as a countermeasure to bioterrorism. I also want to urge the committee to adopt a goal to find broadly applicable countermeasures and to look for products that can

save lives today (and not just those that will save lives years from now) as you seek to ensure the viability of our Strategic National Stockpile (SNS).

Since joining Novo Nordisk in March of this year, I have been extensively involved with the business development, regulatory approval process, and federal procurement issues related to the potential sale of Novo Nordisk's innovative therapeutic treatment, NovoSeven®, for trauma victims. I have personally used NovoSeven to treat bleeding patients since its FDA approval in the late 90s, and have knowledge of NovoSeven from a research perspective that dates to the early 1990s. I also have extensive experience in treating bleeding patients of all varieties in my roles as an emergency department physician, as Director of the Central Virginia Bleeding Disorders Center at the Medical College of Virginia of Virginia Commonwealth University in Richmond Virginia, as Professor of Medicine and Pathology at the same institution and as a Medical Corp officer in the United States Army mobilized for Operations Desert Shield, Desert Storm, Noble Eagle, Enduring Freedom and the Kosovo Campaign.

Novo Nordisk is an established pharmaceutical company and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. In addition, Novo Nordisk has a leading position within areas such as hemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society.

With a U.S. base of operations in Princeton, New Jersey, Novo Nordisk employs approximately 20,250 full-time employees in 78 countries, and markets its products in the U.S. and nearly 180 other countries. Novo Nordisk's shares are publicly traded on the New York Stock Exchange (symbol, NVO), as well as the stock exchanges in Copenhagen and London.

The Chemical, Biological, Radiological and Nuclear Threat (CBRN)

As everyone here today knows, the threat of a terrorist attack on the United States involving chemical, biological, radiological, or nuclear weapons is very real. In October 2001, shortly after the 9/11 terrorist attacks on the World Trade Center and Washington, D.C., 5 letters containing anthrax killed five people, sickened nearly two dozen, and required prophylactic antibiotic treatment for 32,000 more. Since the 1980s, terrorist organizations have embraced the use of CBRN threats. For instance, in the last 10 years, the Japan-based Aum Shinrikyo cult has attempted an aerosolized release of anthrax from Tokyo building tops, unsuccessfully attempted to obtain Ebola during an outbreak in Africa and released sarin gas into a subway system. Concern continues to mount about the potential use of CBRN agents against U.S. troops and interests abroad, as well against U.S. civilian populations.

Even small scale use of these agents has the potential for enormous social and economic disruption and exhaustion of local and national resources needed to combat the threat, treat disease and clean up environmental contamination. As a basic first step, therefore, efforts have been made to better understand the scope of each threat and the consequences of an attack in order to prioritize pursuit of defenses against the highest priority agents.

A Multitude of Threats

For biological threats, the CDC has identified and classified over 40 agents in Categories A–C. For a vast majority of these agents, there are no effective preventive vaccines, diagnostic systems or antidotes following exposure.

Several national programs exist to monitor and provide early warning in the case of a terrorism event, including BioWatch and BioSense, as well global programs such as the Emerging Infections Sentinel Networks. In addition to screening the environment for the presence of pathogens, a sudden increase in non-specific syndromes may indicate a bioterrorism event. The recognition of a large number of previously healthy individuals with a common site of exposure presenting with similar symptoms including severe respiratory illness with fever, gastrointestinal maladies, encephalitis or meningitis, neuromuscular illness, fever with rash or bleeding disorders could indicate a CBRN attack. However, the development of rapid diagnostics for both known and unknown threats remains a challenge.

Even before a definitive diagnosis is made, greater problems will arise in identifying, isolating and treating a potentially large numbers of victims and such a situation could develop into a crisis. In the case of a CBRN attack, there will likely be difficulty in diagnosing the causative agent, especially since many of the potential threat agents manifest with very similar symptoms. For this reason, it is critical to develop countermeasures that are broadly applicable, especially in the absence of a diagnosis or in the case of a genetically modified or emerging threat. Further,

countermeasures that are efficacious in treating a variety of ailments are highly desirable since the nature of future terrorist attacks are unknown.

The Need for Broadly Applicable Countermeasures

There are two main strategies to prepare for a CBRN attack. The first is to develop preventatives for the known threat agents, typically vaccines, such as anthrax and smallpox vaccines. This strategy has certain weaknesses. First and foremost, it is effective only against a biological attack, not chemicals or radiation. Second, it works only with previously known and characterized agents. A third major weakness is the monumental difficulty of vaccinating the entire U.S. population against each and every threat agent. Mass vaccinations pose a significant risk/benefit concern with children, the elderly, women of child bearing age and immunocompromised individuals. Lastly, to date, anthrax and smallpox are the only biological threat agents with FDA approved vaccines, and these vaccines are associated with certain limitations on their use. Therefore, it is clear that preventatives alone will never adequately address the CBRN threat.

The other main anti-CBRN strategy is to have available countermeasures for post exposure treatment. There are also certain weaknesses to this strategy. For example, at this point in time, only a few approved therapies exist for exposure to a toxin, chemicals or radiation, and treatment is dependent on identifiable symptoms in the individual patient. There is no approved treatment for any of the hemorrhagic fever viruses. While ribavirin may be used under an Investigational New Drug (IND) protocol for the arenaviruses and bunyaviruses, no such treatment exists for the filoviruses or flaviviruses. Although countermeasures are being pursued that target specific agents, most of these, if successfully developed, will not be available for stockpiling for over a decade. Moreover, many of these agents must be administered within a narrow window of time to be efficacious. Often a definitive diagnosis is needed to decide upon an appropriate countermeasure to administer. The period of latency before symptoms emerge that is associated in particular with biological agents adds a significant hurdle in that without adequate diagnostic tests to detect disease in early stages, by the time the patient exhibits identifiable symptoms, the drugs under development may prove ineffective.

Therefore, today the reality is that therapy following exposure to most CBRN threats will be largely supportive. This leaves us highly unprepared to deal with the casualties following a CBRN attack.

One answer to the difficulties posed above is to have available countermeasures that address common symptoms of CBRN agent exposure.

NovoSeven

This is where our company's revolutionary new drug, NovoSeven, enters the national medical preparedness picture. But first, let me be clear about one thing to the committee today. The primary focus of Novo Nordisk has not been the development of drugs to protect against attack by CBRN weapons. The principal focus of our company has been, and remains, pursuit of innovative bio-pharma products for the commercial market. We are not a "biodefense" company as that term has come to be known in the post-9/11 environment. While we will certainly work diligently to supply NovoSeven for whatever purpose the US Federal Government feels appropriate, our business plan, our executives, and our investors do not see the primary focus of Novo Nordisk, now or in the future, to be the federal market place.

Nevertheless, in the years since the horrific 9/11 attacks and the ensuing threats which our country faces everyday, we have come to realize that one of our commercial products would be a great asset to responding to terrorist attacks.

NovoSeven is a mature medical therapy approved by FDA for use in hemophilia patients, but it could be also be used to save lives in a CBRN attack by treating bleeding disorders caused by a wide array of threat agents. The immense value of NovoSeven as a life-saving therapy for CBRN applications lies in its unique mechanism of action to prevent severe blood loss and extend the window of opportunity for therapeutic intervention. Availability of NovoSeven would make an immediate contribution to enhancing our nation's medical and public health readiness for mass casualty events. To realize these benefits, Novo Nordisk believes that NovoSeven should be considered as a key component of the comprehensive national plan for readiness against a CBRN attack and as a key asset to the SNS.

Since it reached the general market in 1996, over 700,000 doses of NovoSeven have been administered. NovoSeven is currently only approved by the FDA for use in hemophilia A and B patients and is 80-90% effective in treating bleeding episodes. NovoSeven is also approved for use in treating bleeding episodes in acquired hemophilia, Factor VII deficiency and Glanzmann's thrombasthenia in the European Union. Other reported uses in normal patients include individuals with trauma or surgery-associated hemorrhage, intracerebral and pulmonary hemorrhage, or bleed-

ing following bone marrow transplantation. Pivotal phase three trials to support applications for indications in the areas of intracerebral hemorrhage and trauma should begin this calendar year in the US, Canada and Europe. An application for FDA approval for the use of NovoSeven in inhibitor patients requiring surgery is currently pending. Plans are being prepared for a discussion with the FDA on the most appropriate pathway for approval of NovoSeven in pulmonary hemorrhage. Novo Nordisk currently holds IND protocols for other uses of NovoSeven including treatment of bleeding in trauma patients and also thrombocytopenia following chemical or radiological exposure.

NovoSeven has an excellent safety profile, since it is a recombinant product and contains no human products. To produce NovoSeven, the gene for human Factor VII was cloned and expressed in baby hamster kidney cells. The recombinant protein is secreted into the media of the cells from which it is purified using a chromatographic purification process. The purification process has been demonstrated to remove any potential contaminating viruses. Further, no human serum or other proteins are used in the manufacturing of this product.

NovoSeven has been found to be safe and effective in both patients with bleeding disorders and those without pre-existing coagulopathy. Even following repeated administration, there is no evidence of antigenicity, or immune responses to the product, in patients receiving NovoSeven. NovoSeven has been shown to be effective when other treatments fail, are contraindicated, or blood products are unavailable. NovoSeven has a very low frequency of serious adverse events, remaining around 1% following administration of greater than 700,000 doses. Even when very high 'mega' doses of the drug are administered, it appears to be safe. The most important serious adverse event type for NovoSeven is thromboembolic (i.e. serious blood clotting) events; however, only 104 thromboembolic events have been reported following administration of more than 700,000 doses of NovoSeven. This represents an event rate of two thromboembolic events per 10,000 standard NovoSeven doses—a very low frequency considering the clinical severity of diseases in which NovoSeven is being used. Of further importance, the mode of action of NovoSeven localizes the coagulation effects to the area of injury, thus avoiding systemic activation of clotting and the risk of thrombosis.

Use of NovoSeven Against CBRN Agents

Many companies have the capability to develop new products to protect against attack by biological and chemical weapons or other dangerous pathogens. A few firms, such as Novo Nordisk, have already done so. In fact, Novo Nordisk is one of the largest and most qualified companies to express interest in Project BioShield to date. Should the federal government work with Novo Nordisk to negotiate a viable business relationship with respect to the federal government's purchase of NovoSeven, it will send an extremely powerful, positive signal to similarly qualified companies to enter this marketplace. Of course, the failure of this endeavor could have a negative effect on the goal of stimulating greater interest of large biopharma companies.

NovoSeven could be immediately tapped for filling current shortfalls in our medical defense arsenal. NovoSeven has the potential to be broadly used against bleeding disorders caused by a chemical, biological, radiological or nuclear attack. The use of NovoSeven might be particularly useful in the immediate time period following a CBRN attack—before confirmed diagnosis of the attack agent or in the case of unknown diagnosis. Further, NovoSeven could be a critical component of the SNS for treatment of diseases, such as the hemorrhagic fever viruses, that have no other treatments. NovoSeven could also be useful in combination with other therapies in difficult patient cases or with genetically modified or emerging threats for which treatment is unknown. NovoSeven will also likely be used by health care providers in patients that have not received the proper treatment in time to stop the severe end-stage bleeding disorders associated with CBRN attacks. Additionally, even where there is a definitive diagnosis, cessation of bleeding would be a valuable and necessary component of a combination of treatments to enhance survival in victims with hemorrhagic symptoms.

Proposed BioShield Implementation Improvements

Recognizing the need to protect its citizens, the U.S. government is committed to spurring CBRN medical countermeasure development through policy means. The Project BioShield Act of 2004 provides new and necessary tools to improve medical countermeasures protecting Americans against a CBRN attack.

Although Project BioShield is a commendable first step, a number of issues concerning BioShield and the SNS deserve further attention. More specifically, the current implementation scheme for BioShield can be improved upon to maximize the authorities granted through the legislation and to more rapidly and effectively bol-

ster the SNS. First, the procurement of countermeasures is limited by the current implementation scheme because there must be a call for material threat assessments against a specific agent, followed by a call for a countermeasure against that threat. Unfortunately, this process is not well-suited to countermeasures such as NovoSeven that are effective for treatment of multiple threats.

Further, the current procurement process precludes products with a significant commercial market. This provision of the legislation serves as a disincentive to companies with marketable products with potential broad applications in the CBRN arena (e.g., broad spectrum antibiotics) and deters their participation in CBRN medical countermeasure research and development. While many of the specifically targeted countermeasures are in such early stages of development that it will be years before they can be stockpiled under IND status and then subsequently licensed, it is likely that mature technologies exist that are approved for other uses that could also provide *near-term* solutions to the country's CBRN defense needs if given the opportunity to compete for Project BioShield contracts. Pursuing FDA-approved drugs for other CBRN related indications could significantly expedite the regulatory and development process since these products have already been used in humans.

With the two changes identified above, BioShield is more likely to meet its goal of establishing a stockpile of vaccines and therapeutics to counter various CBRN agents. Our nation should acquire effective countermeasures **now**, while still promoting an innovative pipeline of countermeasures, thereby stockpiling a broad range of products that defend against immediate and future threats.

In closing, let me say that I hoped I have provided you with valuable information about the use of NovoSeven as a broadly applicable countermeasure and also about changes to the legislation that represent good, sound public policy that will enhance US security. I look forward to hearing the committee's thoughts and answering any questions the members may have.

Thank you again for this opportunity to testify today.

Mr. KING. Mr. Michael Greenberger.

STATEMENT OF MICHAEL GREENBERGER

Mr. GREENBERGER. Thank you, Mr. Chairman. My name is Michael Greenberger. I am director of the University of Maryland Center for Health and Homeland Security. I am not a scientist or involved with any corporation; I am a lawyer by training and a professor of law. But I do work extensively with researchers who have been given substantial grants by the National Institute of Allergy and Infectious Diseases to develop countermeasures for Class A, B, and C agents on the CDC's lists.

My focal point of what I would like to say to you in this brief time is I think emblematic of the difficulties with Project BioShield is that nothing, none of that \$5.6 billion, can be released until the Department of Homeland Security makes a material threat assessment. You heard time and time again worries about pandemic flu and the avian flu, and the answers that we do not have an industrial base. The \$5.6 billion was intended to create an industrial base. After 1 year after BioShield has been passed, almost 4 years after 9/11, 5 years after the Defense Science Board has made findings in this regard, the Department of Homeland Security, its one responsibility that it is the leader of under BioShield, has made four material threat assessments for anthrax, smallpox, botulism toxin, and radiological and nuclear devices.

Dr. Carr is talking about something that his company has that is principally designed to deal with hemorrhagic fevers. You, Mr. Chairman, opened the meeting up by talking about Marburg and ebola hemorrhagic fevers. After 1 year, the hemorrhagic fever is not on the material threat assessment list; therefore, the entire country who is worried about this is being told do not invest your time,

your research time, your development time, your manufacturing time in hemorrhagic fevers.

Dr. Vitko says—first in prior testimony he said by the end of fiscal year they will—which I take it to mean before October 1st, hemorrhagic fevers will be on the list of—material threat assessment list. Today we learned it will be at the end of the fiscal year. These—nothing can be done until these items are listed. They have talked about a 3—or 4-month assessment to get a draft up with regard to meetings. Dr. Morr says in Afghanistan they found in the tents of al-Qa’ida documented information that they intend to use tularemia and plague. Tularemia and plague are not yet material threat assessments.

When the BioShield statute was set up, this wasn’t supposed to be some complicated hearing endorsed by substantial evidence and reviewed by courts of appeals. My reading of the statute is this was a very preliminary assessment that was supposed to be made, the Defense Science Board, the Center for Disease Control. Congressman Weldon talked about Jessica Stern, who has one of the leading scholarships in this area. Her book was published in 1999. She lists 60 agents that need to be considered.

Now, Dr. Vitko said the CDC’s work is a good starting point. They are going to add to it. Well, the CDC, by however you count, is at least 33 agents, and they are going to add to it? How long is that going to take? And if there are surprises, he said, some of the CDC’s agents aren’t going to be listed. That is going to be a very big surprise.

I can tell you that the scientists I work with are in the elementary stages of developing vaccines for tularemia, plague, smallpox, anthrax, avian flu, and many other threats to this country. It goes—even if they are successful, it is a long step between the research and going through all the clinical trials and then getting the stuff manufactured. And if we can’t do this fundamental work, which is the one responsibility the Department of Homeland Security has, in all this time, that is worrisome. And I think this committee should grab the Department of Homeland Security by the scruff of its neck and get these assessments made.

The final point I would make in this regard is that there are—if we want to create an industrial base, we must move more quickly. I know there is worry about coordination between Department of Homeland Security and HHS. To my mind, there is too much coordination. There are a lot of committee meetings, and we have to wait until everybody is available for the meeting.

I am reading a biography now of Winston Churchill. He would have not taken 3 to 4 months to figure out material threat assessments when the blitz was happening in London.

We are essentially—speaking of London, we are in our own kind of blitz. We must move more quickly. There are many problems with BioShield. I would be happy to answer other questions, but I think this is emblematic of the maladministration of a wise program proposed by the President and passed bipartisan by this Congress.

Mr. KING. Thank you for your understated testimony. Thank you, Mr. Greenberger.

[The statement of Mr. Greenberger follows:]

PREPARED STATEMENT OF MICHAEL GREENBERGER

My name is Michael Greenberger.

I want to thank the subcommittee for inviting me to testify on the important issue that is the subject of today's hearings.

From 1999 to 2001, I served as Justice Department's Principal Deputy Associate Attorney General. Included within my portfolio of responsibilities were several counterterrorism projects concerning both law enforcement and public health policy, including organizing the first nationwide counter terrorism field exercise, "TOPOFF I."

I now serve as a Law School Professor at the University of Maryland School of Law and, since May 2002, as the Director of the University of Maryland Center for Health and Homeland Security.

At the School of Law, I have designed and teach two courses focused on legal and public policy issues concerning counterterrorism: (1) "Homeland Security and the Law of Counterterrorism," which addresses the legal framework surrounding the response to the terrorist threat facing the United States, including the Project BioShield Act of 2004; (2) "Homeland Security—The Interdisciplinary Study of Crisis and Health Consequence Management Policy in the Era of Counterterrorism" which is open to students from all of the University of Maryland professional schools and explores public health policy implications of counterterrorism strategy, including the development of a stable biodefense vaccine industry.

The University of Maryland Center for Health and Homeland Security (CHHS) serves as an advisor on public health emergency planning to various state and local agencies. CHHS also works closely with: (1) the Center for Vaccine Development (CVD) at the University of Maryland School of Medicine, which is the only university vaccine center in the world engaged in the full range of vaccinology: from basic science through vaccine development, clinical evaluation and field studies, including groundbreaking work on biodefense vaccines; and (2) the Mid-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases (MARCE), one of eight Regional Centers of Excellence (RCE) funded by the National Institute of Allergy and Infectious Diseases (NIAID). MARCE is headed by Dr. Myron Levine, the director of CVD. MARCE is now in the process of researching and developing new biodefense vaccine products to be used as prophylaxis against a broad array of biological agents.

Through CHHS's work with CVD and MARCE, CHHS has organized symposia¹ and I have written several articles² addressing the substantial economic, regulatory, and legal roadblocks to creating biodefense vaccines.

One of the bright milestones toward the development of a vibrant biodefense vaccine industry was the passage of the Project BioShield Act of 2004. That statute was designed "to provide protections and countermeasures against chemical, radiological, or nuclear [CBRN] agents that may be used in a terrorist attack against the United States."³ The most prominent parts of that legislation were its procurement provisions designed to address the key significant impediment to biodefense vaccine production, lack of a significant market.⁴ These provisions encourage the development of effective vaccine countermeasures by establishing a Special Reserve Fund of \$5.6 billion to be spent over the next ten years to purchase for the Nation's Strategic National Stockpile (SNS) the "next generation of countermeasures against" a broad array of chemical, biological, radiological, and nuclear agents, all of which were seen by Congress as weapons that could be deployed against the United States in the War on Terror.⁵ Due to the substantial expense and risk of bringing a vaccine to market, along with the infrequency with which these diseases occur naturally, phar-

¹ Symposium, *Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development*, at the University of Maryland School of Law, June 9, 2004.

² Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7 (2005) (hereinafter Greenberger, *800 Pound Gorilla*); Michael Greenberger, et al., *The Threat of Smallpox: Eradicated but not Erased*, J. HOMELAND SEC. Feb. 2004, <http://www.homelandsecurity.org/journal/Articles/displayarticle.asp?article=103>; ELIN GURSKY & MICHAEL GREENBERGER, ANSER INSTITUTE FOR HOMELAND SECURITY, INSTITUTE COMMENTARY: SUPPOSE THEY GAVE A CIVILIAN SMALLPOX VACCINATION PROGRAM—AND (ALMOST) NOBODY CAME? (Feb. 20, 2004), http://www.homelandsecurity.org/Hls/commentary/gursky_smallpox_commentary_20feb04.html.

³ Project BioShield Act, Pub. L. 108–276, 118 Stat. 835 (2004).

⁴ Frank Gottron, *Project BioShield*, CRS REP. NO. RS21507 (Updated December 27, 2004), at 1.

⁵ United States Department of Health and Human Services, HHS Fact Sheet—Project BioShield, July 21, 2004, <http://www.hhs.gov/news/press/2004pres/20040721b.html>

maceutical manufacturers have little to no incentive to invest without BioShield funds.⁶

In order for the BioShield Special Reserve Funds to be released for the purchase of a countermeasure for SNS, a series of actions must occur.⁷ However, the first action (and the one on which all later actions are based) is that “the Homeland Security [DHS] Secretary, in consultation with the [HHS] Secretary and the heads of other agencies as appropriate,” must make a “determination” of “current and emerging threats of CBRN agents” that “present a material threat against the United States. . . .”⁸ Once that “material threat assessment” is made various government agencies, up to and including, the President, through a series of decisions then determine whether promising countermeasures may be purchased with the special reserve funds to address those identified threats.⁹

The BioShield Act established no procedure for DHS to employ in supervising the making of the material threat determinations. Despite what was an obvious Congressional invitation to summarily determine what are the widely recognized CBRN threats to the United States, DHS has employed an opaque, highly bureaucratized, relatively lengthy process for determining material threats. Over the course of the past year, this cumbersome and poorly delineated administrative process has led to only four material threat determinations. Findings have been made that Anthrax, Smallpox, Botulinum toxin and radiological/nuclear devices pose a material threat to the United States. DHS officials have promised that by the close of this fiscal year material threat determinations will be made concerning plague, tularemia, and viral hemorrhagic fevers.¹⁰

Because there have only been material threat determinations pertaining to four CBRN agents, BioShield’s Special Reserve funds can only be used for countermeasures directed to those agents. Accordingly, three contracts have been let over this last year, two directed to the purchase of anthrax vaccines¹¹ and one for the delivery of pediatric doses of liquid potassium iodide.¹² Even if a promising countermeasure were to meet the other requirements for purchase under the statute, it would not be eligible for procurement if there were no corresponding finding that the agent to which it was directed was a “material threat.”

DHS’s lassitude in supervising the making of material threat findings is mystifying. The legislative history of the statute is replete with references to a myriad of agents, beyond the four agents identified, posing a substantial threat to the United States.

Moreover, the Center for Disease Control (CDC) has a long established and widely recognized hierarchy of highly damaging biological agents that are likely to be deployed by terrorists against the United States. CDC’s Category A agents, ranked as the most dangerous to the United States, include Anthrax, Botulism, Plague, Smallpox, Tularemia, and Viral hemorrhagic fevers. Only three of those agents have as yet been identified under the BioShield bureaucracy as posing a material threat. DHS has assured committees of Congress that it will by the end of this fiscal year make findings on the remaining three Class A agents identified by CDC.

When you look at the Category B and C agents identified by CDC, there are total of more than 33 agents which ultimately will need to be addressed with medical

⁶*BioShield: Countering the Bioterrorist Threat: Hearing Before the House Select Committee on Homeland Security*, 108th Cong. (May 15, 2003) (statement of Alan Pemberton, Pharmaceutical Research and Manufacturers of America), available at http://www.globalsecurity.org/security/library/congress/2003_h/5-15-03_pharmaceutical.pdf; Frank Gotron, *Project BioShield*, CRS REP. NO. RS21507 (Updated December 27, 2004), at 1–2.

⁷Project BioShield Act of 2004, Pub. L. 108–276, § 3(a)(2), 118 Stat. 835, 843–52 (2004); United States Department of Health and Human Services, Procurement Items—BioShield Funds, March 23, 2005, <http://www.hhs.gov/ophep/bioshield/bioshieldfunds.html>.

⁸Project BioShield Act of 2004, Pub. L. 108–276, § 3(a)(2), 118 Stat. 835, 844 (2004).

⁹Project BioShield Act of 2004, Pub. L. 108–276, § 3(a)(2), 118 Stat. 835, 843–48 (2004); United States Department of Health and Human Services, Procurement Items—BioShield Funds, March 23, 2005, <http://www.hhs.gov/ophep/bioshield/bioshieldfunds.html>.

¹⁰*Combating Weapons of Mass Destruction: Hearing Before the Subcommittee on National Security, Emerging Threats, and International Relations of the H. Comm. Of Government Reform*, 109th Cong. (June 15, 2005) (testimony of Dr. John Vitko, Jr., Director, Biological Countermeasures Portfolio, Science and Technology Directorate, Department of Homeland Security), available at <http://reform.house.gov/UploadedFiles/ST.Govt%20Ref.Vitko.06-14-05.pdf>.

¹¹Press Release, United States Department of Health and Human Services, HHS Buys New Anthrax Vaccine for Stockpile (Nov. 4, 2004), <http://www.hhs.gov/news/press/2004pres/20041104a.html>; Press Release, United States Department of Health and Human Services, HHS Awards BioShield Contract for AVA Anthrax Vaccine (May 6, 2005), http://communitydispatch.com/artman/publish/article_961.shtml.

¹²Press Release, United States Department of Health and Human Services, HHS Awards BioShield Contract for Liquid Potassium Iodide (March 18, 2005), <http://www.hhs.gov/news/press/2005pres/20050318.html>.

countermeasures.¹³ At the rate the “material threat” findings have been made to date, it could be years before BioShield procurement funds can be used to purchase products designed to counter the as yet undesignated agents.

Leaving CDC’s findings to the side, scholarship on terrorist threats abound with long standing and well recognized findings about a significant number of CBRN agents likely to be deployed against the United States. For example, Jessica Stern in her 1999 classic, *The Ultimate Terrorists*, lists two dozen chemical agents that have been historically deployed by terrorists going all the back to World War I.¹⁴ Not one of these chemical agents has been certified under DHS’ leadership. Nor has DHS even committed to making such designations in the future.

Quite ironically, under other provisions of the BioShield statute concerning HHS funding for research (which does not require a “material threat” finding), grants have been made for the development of countermeasures relating to tularemia, Ebola, and plague.¹⁵ Yet, none of these agents has yet been designated as a material threat. If HHS has already commenced funding for research in this area, one would assume that there is substantial evidence available to DHS demonstrating that these agents should be so designated.

From CHHS own experience, substantial NIH funding outside of the BioShield appropriations is being committed to the development of medical countermeasures not yet declared to be “material threats”. For example, MARCE is researching countermeasures for tularemia as part of a five-year, grant from NIAID, which is supported by funding wholly apart from monies appropriated under the BioShield statute.¹⁶ Simultaneously, plague vaccine research is being performed in the laboratories of James Nataro, M.D. at the CVD that is funded by funded by a National Institutes of Health U19 grant,¹⁷ again a project being done wholly apart from the BioShield Act.

The BioShield Act is an impressive starting point for the creation of a vibrant bio-defense vaccine industry. It has many problems that must be corrected both administratively and legislatively.¹⁸ I would be happy to address each of those issues with you today. However, only one of those problems deals directly with DHS, the agency over which you have direct oversight responsibilities. DHS bureaucratic quagmire in identifying CBRN agents posing a material threat to the United States (thereby delaying the use of procurement efforts for well recognized CBRN dangers to this country) is a matter that deserves your full attention.

This problem does not require a legislative fix. What it requires is prodding the agency to abandon an administrative morass. It requires directing the agency to follow the well worn path already trodden through scholarship and the work of the CDC to quickly list the full panoply of CBRN agents. Such an expedited effort would be an encouragement to both researchers and the vaccine industry that a broad array of efforts might be funded over the next decade by the BioShield Special Reserve Fund.

Finally, this subcommittee should be aware that the legislation recently introduced as a corrective to the Bioshield Act (S. 975, or the Project Bioshield II Act of 2005) places the major procurement responsibility principally in the hands of DHS, reducing substantially the role of HHS.¹⁹ This displacement of HHS is supposedly called for because industry supporters of Bioshield II view “HHS as having a contentious relationship with the biopharma industry.”²⁰ However, given the dif-

¹³ CDC, Bioterrorism Agents/Diseases (Nov. 19, 2004), <http://www.bt.cdc.gov/agent/agentlist-category.asp>.

¹⁴ JESSICA STERN, *THE ULTIMATE TERRORISTS* 24–25 (1999).

¹⁵ Press Release, United States Department of Health and Human Services, NIH News, NIAID Awards First \$27 Million Using New Bioshield Authorities (May 9, 2005), <http://www.nih.gov/news/pr/may2005/niaid-09.htm>.

¹⁶ Virginia Bioinformatics Institute, Mid-Atlantic Regional Center of Excellence, <https://www.vbi.vt.edu/article/view/426>.

¹⁷ Center for Vaccine Development, University of Maryland School of Medicine, Nataro Lab, <http://medschool.umaryland.edu/cvd/natarolab/natarolab.html>

¹⁸ For a complete description of the problems with implementing the BioShield statute, see *Crossing the Valley of Death: Bringing Promising Medical Countermeasures to BioShield: Hearing Before the Senate Health, Education, Labor and Pensions Subcommittee on Public Health*, 109th Cong. (June 9, 2005) (statement of Dr. Phillip Russell, Major General, Retired, U.S. Army), http://help.senate.gov/testimony/t319_tes.html. I agree with almost all of Dr. Russell’s assessments. For a proposal to resolve indemnification problems identified by Dr. Russell and others, see Greenberger, *800 Pound Gorilla*, *supra* note 2.

¹⁹ ARNOLD & PORTER, LLP., CLIENT ADVISORY: “BIOSHIELD II” BILL WOULD EXPAND INCENTIVES TO DEVELOP BIODEFENSE COUNTERMEASURES 1 (May 2005), [http://www.arnoldporter.com/pubs/files/A&PAdvisory-BioshieldII\(0505\).pdf](http://www.arnoldporter.com/pubs/files/A&PAdvisory-BioshieldII(0505).pdf).

²⁰ *Id.* at 2.

difficulties DHS has had with effectively carrying out its single major mission under the existing legislation, Congress should think long and hard before it puts the entire biodefense vaccine apparatus under DHS.

TESTIMONY SUMMARY

The Department of Homeland Security has employed an opaque, highly bureaucratized, and lengthy process under the Project Bioshield statute for determining those chemical, biological, radiological and nuclear (CBRN) agents which pose "material threats" to the United States. BioShield's Special Reserve funds can only be used for countermeasures directed to those agents designated by DHS as material threats. DHS's decision-making apparatus has to date only made material threat determinations pertaining to four CBRN agents. It is well understood both within the Center for Disease Control and in the scientific research community that there are as many as 60 agents that now pose a "material threat." Even if a promising countermeasure were to meet the other requirements for purchase under the statute, it would not be eligible for procurement because of a lack of a material threat finding. At the rate the "material threat" findings have been made to date, it could be years before funds will be eligible to purchase products designed to counter those as yet undesignated agents. Moreover, the delay in recognizing agents as a material threat amounts to a disincentive to both researchers and the vaccine industry to devote resources to CBRN agents that are not as yet designated as material threats.

Mr. KING. The Chair now recognizes Dr. Richard Hollis, the chief executive officer of Hollis-Eden Pharmaceuticals.

STATEMENT OF RICHARD B. HOLLIS

Mr. HOLLIS. Thank you, Mr. Chairman, members of the committee. My name is Richard Hollis. I am chairman of Hollis-Eden Pharmaceuticals, the manufacturer of a product called NEUMUNE. It is the first drug that is specifically being developed as a medical countermeasure to acute radiation syndrome, commonly referred to as radiation sickness, as a result of nuclear terrorism.

And I also ask that I please have my entire statement entered into the record.

Mr. KING. Without objection.

Mr. HOLLIS. All of our Nation's leaders from the President on down have concluded that the greatest threat to our Nation is nuclear proliferation and nuclear materials in the hands of a terrorist. The head of the Domestic Nuclear Detection Office recently said there is a 100 percent chance someone will try to attack the U.S. with a nuclear weapon in the next 5 to 10 years. Also, in a recent televised interview the Chairman and Vice Chairman of the 9/11 Commission both stated that not only is a nuclear detonation in one or more of our inner major cities possible, but it is also probable.

Imagine what would happen if a small nuclear bomb went off in Washington, New York, or Los Angeles, a bomb similar to the mockup that Congressman Weldon uses to demonstrate how small these devices actually are. The death toll from the detonation of a relatively small nuclear device in one or more of our major cities would be devastating. Medical reports indicate the vast majority of those who are killed, hundreds of thousands would die from acute radiation syndrome, also known as ARS.

When humans are exposed to radiation injury, the bone marrow is incapacitated, and it doesn't have the ability to produce red blood cells that carry oxygen, platelets that help fight blood clots, and

white blood cells that help fight infection, and people will die from bleeding and infection.

The sad thing is the overwhelming majority of these people could be saved if the government was better prepared to respond to a nuclear scenario deploying the appropriate medical countermeasures. Our inability to manage the aftermath of a nuclear attack is now caused by our failure to deploy a drug for acute radiation syndrome. Now, if you can imagine that you could rapidly distribute a drug to the people and give it to them much like soldiers with autoinfectors following a chemical attack; and imagine if that drug could stimulate the body to make white blood cells to fight infection and platelets to protect you from bleeding; and, most importantly, imagine that up to 90 percent of the people who received the treatment could survive. This is not a fantasy. We have an experimental drug with the potential to treat ARS that could be in the strategic national stockpiles as early as next year. And primate tests done under the Department of Defense oversight using lethal doses of radiation, this drug, NEUMUNE, has been shown to increase survival rates up to 90 percent. To date, it has no serious side effects, it is inexpensive, and it can be self-administered without hospitalization.

There is currently no therapy in the stockpile for acute radiation syndrome. Prussian Blue and potassium iodide, currently stockpiled, both address long-term health impacts; they do not address ARS. What we need is an ARS therapy, and so let me be blunt. Every treatment of this drug or something like it given to a victim of such an attack stands to save a human life. However, HHS has continued to delay the procurement of an effective radiation drug for ARS.

I would submit that the key question for this committee is: Given the nuclear threat is the greatest one that we face, and given that more than a million lives per detonation may be on the line, and given that a promising, effective medical countermeasure to a nuclear attack to treat ARS is close to fruition, and it is now 4 years after 9/11, why is this drug not a top priority to be deployed to protect the American public?

The failure here reflects a series of fundamental disconnects between HHS and DHS's role under BioShield. Our BioShield priorities are not coordinated with our national security priorities. As experts interviewed on Meet the Press just this past Sunday stated, our DHS spending is still not based on prioritized risk assessment.

Overwhelmingly, experts agree that the greatest threat facing this Nation is a nuclear threat. That said, DHS and HHS have committed billions of dollars to second- and third-generation products such as anthrax drugs, and we don't even have a first-generation—or RFP out issued for a first-generation acute radiation syndrome drug. This is in part because DHS has failed to publish a prioritized list of BioShield threats. This not only causes confusion, but also creates market uncertainties, exactly the opposite of what BioShield was intended to do, which is to guarantee markets. As a result, since the passage of BioShield, our company has lost over \$600 million in market capitalization. There needs to be better transparency and leadership in implementing BioShield.

At the same time, DHS planned nuclear threat efforts are based on assumptions that do not reflect the postnuclear reality. We can't evacuate hundreds of thousands or a million people without an infrastructure. We can't treat people in medical facilities that will be overwhelmed. We can't treat people without an acute radiation syndrome drug. And we can't deploy medicines that need to be given to victims immediately after an incident.

Our nuclear response planning should focus on getting effective ARS treatments out to the greatest number of victims in the fastest way possible. This is detailed in my full written testimony.

So, in closing, how will our leaders try to explain why so many people died unnecessarily from a nuclear 9/11 when experts are predicting this nightmare scenario and we failed to prepare our Nation by providing and forward-deploying a drug that could possibly save millions of lives? So I ask your help today in ensuring that we look carefully at why this country remains unprepared to deal with its greatest threat, that of a nuclear detonation on our soil.

We all know that the terrorists are racing to acquire nuclear weapons, and I want to assure the committee and the government and the people of America that Hollis-Eden is racing to develop NEUMUNE. But our political leaders must also ensure that HHS and DHS join that race, because it is the one race we have no choice but to enter. Last week in London there were multiple bomb blasts—I am wrapping this up—and the world was lucky that those bomb blasts were not nuclear. So the question is, can we be so lucky next time?

So, Mr. Chairman and members of the committee, I want to thank you for the honor of allowing me to testify today, and I hope you agree that Hollis-Eden is a role model for Project BioShield and what Congress intended this legislation to achieve, and that is to create innovative new pharmaceutical drugs to mitigate the medical consequences of weapons of mass destruction. Thank you very much.

Mr. KING. Thank you, Mr. Hollis, especially for giving us the benefit of your own dealings with the Federal Government.

[The statement of Mr. Hollis follows:]

PREPARED STATEMENT OF RICHARD B. HOLLIS

Mr. Chairman, Ranking Member Pascrell, distinguished members of the Committee:

Thank you for the opportunity to testify before you today. Before I begin, allow me to thank you personally for your longstanding leadership, both as a Committee and individually, to help safeguard this nation against terrorism, and specifically against the threat posed by weapons of mass destruction.

My name is Richard Hollis. I am Chairman and Chief Executive Officer of Hollis-Eden Pharmaceuticals. Hollis-Eden is a San Diego-based Biotechnology Company founded in 1994 and publicly traded on the NASDAQ stock exchange since 1997. Hollis-Eden has under development a number of proprietary immune-regulating hormones, compounds that are key components of the human immune system. We believe that by properly utilizing these hormones we can help the body to mount an appropriate immune or metabolic response to a number of different diseases or challenges. Specifically, we have developed and tested our compounds for the potential treatment of Acute Radiation Syndrome (ARS, or what is commonly known as "radiation sickness"), among other possible applications.

THE NUCLEAR THREAT

The President of the United States, the Vice President, the 2004 Democratic candidate for president Senator Kerry, scores of military leaders, leaders from the medical and scientific community, the intelligence agencies, and leaders in homeland security, as well as the chairman and Vice Chairman of the 911 commission have all publicly stated that the greatest threat to this nation is nuclear proliferation and nuclear material in the hands of a terrorist. In fact, the Director of the Domestic Nuclear Detection Office at DHS recently stated that, "There is a 100 percent chance someone will try to attack us with a nuclear weapon in the next five to 10 years."

Imagine that a small nuclear bomb were to go off in Washington or New York or Los Angeles. The bomb is similar to the "mock up" Congressman Curt Weldon often uses to demonstrate how small these devices can be.

The results of such an attack on this nation would be devastating. By extrapolation, the Department of Homeland Security's Nuclear National Planning Scenario (NNPS)¹ estimates that the number of lives lost from a terrorist attack on a major U.S. city could be as high as one million or more people per detonation.

Contrary to popular belief, the vast majority of the victims of a terrorist nuclear attack would die not from the blast, but from Acute Radiation Syndrome (ARS). ARS is the result of radiation-induced bone marrow damage. Specifically, ARS is characterized by the loss of infection fighting cells and clotting elements that are produced in bone marrow. This loss of the body's ability to fight infection and prevent bleeding is believed to be the leading cause of sickness and death in the event of a nuclear attack.

In fact, expert estimates of the medical consequences from a nuclear bomb indicate that ARS would likely kill three to five times as many people as the initial blast. For example, the British Medical Journal recently estimated that a 12.5 kiloton bomb detonated in New York City would kill at least 50,000 people instantly. These 50,000 victims would be beyond help. However, the vast majority of victims—between 200,000 to 700,000 people—would die days or weeks later from the effects of ARS.

The sad fact is that the overwhelming majority of these people could be saved if the federal government was better prepared to respond to a nuclear scenario, including deploying the appropriate medical countermeasures.

OUR INABILITY TO MANAGE THE AFTERMATH OF A NUCLEAR ATTACK IS CAUSED BY OUR FAILURE TO DEPLOY A DRUG FOR ARS

No city has the medical surge capacity to handle the massive numbers of ARS casualties: In the wake of a nuclear attack on a major city, medical facilities will be immediately overwhelmed. Adequate hospital and other clinical medical facilities of most large cities are already utilized at or near full capacity. A nuclear attack will destroy scores of beds and take others off-line because they will be in contaminated areas. This would mean little meaningful ability for hospitals to treat the victims of a nuclear blast.

In New York, for example, a study published in the *British Medical Journal* recently estimated that approximately 1,000 hospital beds would be lost in a nuclear blast and an additional 8700 beds would be contaminated from radiation fallout. Additionally, the bulk of any region's medical personnel—doctors, nurses, technicians, EMT's—are located in the heart of the area most likely to be targeted by such an attack. Most of these medical personnel would be victims of the attack and would not be mission ready to treat other victims.

Additionally, in the wake of an attack, we would expect to see hundreds of thousands of "worried well" flood medical facilities. These people will fear that they have been exposed to radiation and they will seek treatment from whatever medical facilities remain. There is no inexpensive, fast and accurate method to determine the level of radiation exposure and triage radiation victims. This will only complicate the difficult task of determining who is among the worried well, who is sick but can be saved, and who is beyond help. The burden of tens or hundreds thousands of worried well, on top of hundreds of thousands of ARS victims, will immediately overwhelm area medical facilities. The 2004 influenza vaccine shortage gives only a hint of the mass panic and possibly violent demand for medical services that would ensue after a nuclear attack.

Because regional medical facilities will be overwhelmed, one plan is to ship victims to distant care, which will only increase death rates: Because medical resources in the area of any attack will be severely degraded and dangerously over-stretched, we

¹The NNPS here refers collectively to The Planning Scenarios, Executive Summaries, The Homeland Security Council (July 2004), and the accompanying Improvised Nuclear Device, Predecisional Draft (undated).

have been briefed by DHS and HHS officials that one element of the plan for handling the injured and dying is to ship them off in buses and trains to remaining medical facilities that are located at a greater distance from the impacted area.

This plan is fundamentally flawed in at least three respects. First, as described in greater detail below, the transportation infrastructure required to move these people will be destroyed or damaged. Second, even if these victims reach medical facilities that have capacity, medical personnel will have little to offer beyond prayers and compassion. Third, and most importantly, because ARS kills by opportunistic infection, putting scores of immune system compromised victims into enclosed buses and trains will only hasten the spread of infection and death. In other words, such evacuation efforts will hurt victims more than they help them.

Without an ARS treatment first responders will be pulled back—not sent in: The typical American believes that if his or her city was hit by a nuclear attack, help, in the form of first responders, military units and medical personnel will come streaming in to assist victims. This ignores the reality that, at present, we have no way to protect first responders from ARS. Because of the lack of protection, we may not be able to afford to risk sending these units into contaminated areas to help victims and to restore order.

We will have to evacuate hundreds of thousands of people within 24 hours, because of radiation: Because there is no approved and effective treatment for people who have been exposed to enough radiation to trigger the onslaught of ARS, the DHS/NNPS is principally focused on evacuation. The NNPS calls for the immediate or near immediate (within 24 hours) evacuation of roughly 450,000 people from the impacted city. The virtual impossibility of such a mass evacuation is self-evident to anyone who has negotiated rush hour traffic in a major American city.

Without an ARS drug, medical personnel will have little to offer victims of radiation: Absent a drug to counter ARS, the only available treatments are bone marrow replacement and/or the administration of a drug approved for use in conjunction with chemotherapy. Both of these courses of therapy will be of little to no use after a nuclear attack. These therapies are highly expensive, making them cost prohibitive for a mass casualty event. Both of these treatments require intensive medical care in a fully functioning medical facility. There simply will not be enough hospital beds and medical professionals to administer these treatments on a mass casualty scale after a nuclear attack. The DHS NNPS states, “The level of care that can be expected may be significantly lower than would normally be expected.”

Victims lucky enough to get themselves to aid facilities will be able to receive help in the form of decontamination. This will help halt further radiation damage but do nothing for the harm from the radiation already received. Absent the deployment of NEUMUNE, even remaining hospitals will have no treatment to offer the mass casualties such an attack will produce. For the vast majority of evacuees from the impacted area, currently planned rescue and medical efforts provided at the periphery will have little impact on mortality. In short, hundreds of thousands of Americans could die of ARS because we have no effective treatment in the Strategic National Stockpile.

AN EFFECTIVE ARS TREATMENT IS NOW AVAILABLE

Now imagine that you could rapidly distribute a drug that people could give to themselves much like our soldiers do with auto-injectors following a chemical attack. Imagine that that drug stimulated the body to make white cells to fight infection and platelets to protect you from bleeding. More importantly, imagine that up to 90 percent of the people who receive this treatment could survive.

In fact, such a drug isn't a figment of the imagination. This drug could be procured today under Bioshield and be in the Strategic National Stockpile as early as next year.

Two weeks after the devastating September 11, 2001 attacks on our country, officials from the Armed Forces Radiobiology Research Institute (AFRRI), a research division of the Department of Defense, approached Hollis-Eden and told us that they wanted to fast track the development of one of our experimental drugs for the treatment of ARS. In some early studies with mice, AFRRI found that this compound saved literally 100 percent of the animals that would have otherwise died from acute radiation exposure. Since that time, AFRRI has continued testing and publishing results in the medical literature on this compound, known as NEUMUNE, for use in mitigating the effects of acute, high-level radiation exposure.

To date, results in over 200 non-human primates treated with NEUMUNE have demonstrated that the investigational drug is safe and effective in the treatment of ARS. In one recent trial, 90 percent of the treated primates survived otherwise lethal doses of radiation, but only 55 percent of the untreated group survived. Ex-

trapolating those results to a nuclear attack on a major American city, one can see how dramatic an effect this drug could have on mitigating human casualties.

Testing to date has also shown that the drug is stable and can be easily stockpiled. In addition, NEUMUNE can be self-administered in the field by victims of such an attack, without the need for supportive medical care. This capability would free up medical resources that will be stretched beyond the breaking point. The drug has also exhibited no significant negative side effects. And, assuming a contract of sufficient size to offer economies of scale, we can provide the drug at a cost akin to that of a standard antibiotic.

Moreover, NEUMUNE can be administered before exposure or for some period of time *after* exposure. The ability to administer the drug before exposure makes NEUMUNE ideal for first responders and military units. Protected by NEUMUNE, such units could safely be sent into the irradiated area carry out rescue, recovery and relief efforts. This ability alone would fundamentally improve our ability to respond to a nuclear attack. More importantly, however, the capability of the drug to be self-administered hours after an attack offer us the potential to save hundreds of thousands of lives if we respond effectively.

Perhaps most importantly, NEUMUNE represents a dramatic breakthrough in our civilian and military security posture when one considers that here is currently *no* drug in the stockpile for ARS.

With much fanfare, the federal government has stockpiled two compounds, potassium iodide and Prussian Blue, to address radiation injuries; neither of these compounds will save the lives of the upwards of one million people that will die from ARS in the wake of a nuclear attack. Potassium iodide blocks the absorption of certain radioactive isotopes that can lead to thyroid cancer. However, the hundreds of thousands of people who will die from ARS within weeks of a nuclear attack will perish long before they can contract thyroid cancer.

The second drug, Prussian Blue, is a dye used for many years by artists which can act as a chelating agent that helps the body rid itself of radioactive isotopes more quickly, thereby reducing the radiation damage to the gut area. However, Prussian Blue has no impact on the two primary causes of death from ARS: opportunistic infection from immune suppression and bleeding caused by platelet loss. In other words, this compound will not materially impact the numbers of people that will die in the immediate wake of a nuclear attack.

The limitations and possibly over reliance on these drugs gives rise for concern by Congress. In connection with a recent Senate oversight hearing on Project Bioshield implementation, Senator Robert Byrd (D-WV) submitted a question for the record to Assistant Secretary Stewart Simonson about the status of the procurement and stockpiling of radiation medical countermeasures. Secretary Simonson responded by highlighting the Department's acquisition and pending acquisition of potassium iodide and Prussian Blue. In addition, he cited the possible emergency off-label use of an existing drug now given to cancer patients undergoing chemotherapy.

In addition to the limitations cited of potassium iodide and Prussian Blue, the response failed to indicate that the cancer therapy, in addition to not having been approved specifically for ARS, is prohibitively expensive for mass casualty treatment, must be given in a highly controlled clinical (hospital) setting, must be refrigerated prior to administration, and would likely need to be given in conjunction with adjunctive therapies, like intravenous platelet administration.

In short:

- Drugs now in the stockpile do not address ARS, which will be the primary cause of death from a nuclear attack.
- We need an ARS therapy.

In contrast—and allow me to say this bluntly—every treatment of NEUMUNE given to a victim of such an attack stands to save a life.

I would submit the key question for the Committee to consider is this: Given that the nuclear threat is the greatest threat we face; Given that more than a million lives may be on the line; Given that a promising effective medical countermeasure to a nuclear attack to treat ARS is close to fruition; And considering the fact that nearly four years after the 9/11 terrorist attacks, why hasn't the procurement of this drug apparently been a higher priority for the federal government?

THE FAILURE HERE REFLECTS A SERIES OF FUNDAMENTAL DISCONNECTS BETWEEN HHS' AND DHS' ROLE UNDER BIOSHIELD

1. Transparency and leadership are lacking:

We have worked in Washington for almost 3 ½ years now meeting with numerous government agencies about biodefense. We have witnessed a clear lack of consensus as to:

- What the government wants;

- How much they will buy;
- What they will spend;
- When they will buy it; and,
- Who is making the decisions?

No one seems to be in charge. Who is ultimately responsible? As discussed in greater detail in the next section of this testimony, when gaps are identified in our defenses, we have seen agencies point the finger of blame at other agencies—rather than aggressively fixing the problem.

2. Our Bioshield priorities are not coordinated with our national security priorities:

There is no apparent linkage between the threats identified for Bioshield purchases and the greatest threats identified by security experts for homeland security:

The 9–11 Commission, the President, the intelligence community, DHS, others agree: greatest threat to our nation is the threat of nuclear terror. However, nearly four years after 9–11, and one year after the passage of Project Bioshield there still is no binding statement that the federal government is seeking to buy a medical counter-measure to a nuclear attack that addresses ARS. In fact, we are still waiting on a promised *draft* RFP.

At the same time, we have purchased and are seeking to purchase counter-measures for a range of biological threats that are important but clearly do not rise to the level of threat that a nuclear attack does. For example DHS and HHS have committed billions on second and third generation anthrax drugs and we still don't have an RFP issued for a first generation ARS therapy. It may be instructive to note that tens of millions of federal dollars have been committed to developing and procuring Ebola vaccines, when to the best of our knowledge Ebola is not easily weaponized and used as a WMD. This should be compared to the all too real and known threat of a nuclear or radiological attack on the United States.

Additionally, there is no single DHS/HHS common list of major WMD threats and intended/desired medical countermeasures to those threats. DHS speaks of one set of threats to the nation—and nuclear is typically first on that list. Meanwhile, HHS procures drugs from a different list, or, at the very least, a list with vastly different priorities. The lack of a list reflects a lack of threat coordination, which hampers our security efforts.

In addition, this lack of a coordinated set of threats to be addressed creates market uncertainties—exactly the opposite of what Bioshield intended. As a result:

- Industry doesn't know what the nation needs to protect itself;
- This leaves the market undefined;
- As a result, industry hasn't become invigorated by Bioshield; and
- Investors are reticent to fund Bioshield ventures.

This climate does not help us deploy medical countermeasures against WMD.

In general, the federal government's Bioshield priorities do not appear to line-up with our national security imperatives.

3. DHS' planned nuclear response efforts are based on assumptions that do not reflect the likely post-nuclear war environment:

Another disconnect is the how DHS plans to respond to a nuclear attack. These plans are fundamental divorced from the reality of the post-nuclear-attack environment.

Because there is no stockpiled way to treat ARS victims, the NNPS focuses on getting people away from radiation contaminated areas as fast as possible. In order to do so, the NNPS calls for the immediate or near immediate (within 24 hours) evacuation of roughly 430,000 people from the impacted city. Let me emphasize that such a Diaspora-scale evacuation is required to reduce the amount of radiation exposure, which is required to prevent ARS, which, in turn, is required because we have no scenario-based, field-ready ARS treatment. Here the NNPS states: "For people in Zones 1 through 5 [heavily irradiated areas] this evacuation. . . is absolutely essential and must take place immediately or it will have a significant impact on the number of lives that will be lost."

These evacuation plans are not grounded in the post-nuclear-attack reality. First, the NNPS states that all infrastructure within 0 mile will be completely destroyed; damage to infrastructure within 3 miles will be severe. Within these areas bridges will be down, tunnels will be flooded, and roads will be damaged or destroyed.

Consider the impact on two of the most likely target cities: Washington, D.C. and New York, N.Y. In Washington, the blast will likely destroy or severely damage roads and bridges that allow passage out from the city to the South and Southwest. Normal prevailing weather conditions will take the fallout plume from Southwest to Northeast. This will eliminate the use of the largest evacuation routes out of the city. These impacts may leave dry-land evacuation routes (e.g., Wisconsin Avenue) that travel to the Northwest as the only passable means of escape. These routes are

heavily congested under normal conditions to say nothing of what conditions would be like in the wake of such an attack.

With respect to the island of Manhattan, it is likely that a terrorist nuclear attack would destroy or render unusable most of the bridges that service the city. In addition, train and vehicular tunnels would likely experience flooding as water flows into the crater formed by the blast. This would be particularly true if the terrorist target was one of the main transit tunnel hubs, such as Grand Central or Penn Stations. These impacts would leave only far northern routes available to those seeking to escape fallout from the attack. Here again, under normal rush hour conditions—with far more means and routes of movement available than an attack would leave—these routes can become parking lots for hours as a result of a mere traffic accident.

In addition, in New York, such impacts would likely strand the eight million people who live on Long Island. Depending on the plume path, Long Island residents could be left with little other means of escaping a certain death from radiation exposure except by sea in whatever form of craft they could find.

In both cities even undamaged evacuation routes will be gridlocked by the impacts of the attack. For a distance of 13 or 14 miles, people who are looking in the immediate direction of the blast will be blinded, most temporarily. Immediate flash blindness to people operating vehicles will cause scores of accidents along key evacuation routes. Additionally, countless people who have been exposed to high levels of radiation will get into their cars and drive to get out of the area. These individuals will find themselves stuck in massive tie-ups. Those who are most irradiated will at some point begin to get very sick and die; some of them will be behind the wheel when this occurs. Their cars—in some cases abandoned and in others wrecked—will only further impede the progress of any evacuation.

The NNPS notes that: “If [the city attacked] has an efficient, functional transportation infrastructure that is not bottlenecked by bridges, tunnels or other major obstructions and a high percentage of the population has access to the system, it is certain that [the high numbers of people exposed to deadly dose levels calculated to occur in the NNPS] will be drastically reduced.” Query, what major American city has such a transportation system on its very best day? (See Graph 1.)

Graph 1: ANNUAL HOURS OF TRAFFIC DELAY PER
TRAVELER: 2003

Los Angeles	93
San Francisco	72
Washington, DC	69
Atlanta	67
Houston	63
Chicago	58
Miami	51
New York	49
Phoenix	49
Philadelphia	38

Source: Texas Transportation Institute 2005.

Further, it is unlikely that the NNPS called for response can be achieved without first responders. Here again, ARS will block rescue and recovery efforts and frustrate the NNPS’ efforts to save lives.

The typical American believes that if his or her city was hit by a nuclear attack, help—in the form of first responders, military units and medical personnel—will come streaming in to assist victims. This is false. Until such time as NEUMUNE is widely deployed, we have no way to protect first responders who enter the irradiated area from falling victim to ARS. Standard issue breathing devices and protective clothing do nothing to protect individuals from deep-body penetrating gamma radiation. According to the NNPS, “First responders may don [protective gear] to prevent internalization of fallout, but [this gear] does not reduce the gamma or neutron dose from external sources of radiation.”

As a result, first responder units will actually be pulled back from assisting victims in the impacted area to a safe distance perimeter. Those few first responders who ignore these orders, and those already in the irradiated area who remain to help victims, will be working in a highly contaminated environment using equipment that is highly contaminated and suffering from “battlefield stress” that also works to diminish the body’s immune system; they will soon begin to suffer from ARS and their mission readiness will decline precipitously as they go from savior to victim.

The NNPS states obtusely, “In a limited manpower situation, where the total integrated dose that can be absorbed by the finite number of trained and equipped response workers is fixed, as it is likely to be during the first few hours [more likely days] after the event, the value of these rescue activities will need to be weighed against those of preventing or reducing the future exposure of people in the high-does fallout regions downwind.” Lara Shane, DHS’ Director of Public Education recently put this more directly in an article in the *National Journal*: in the event of a nuclear attack, “We need people to take care of themselves for 72 hours.” Sadly, this 72 hour timeframe is the period of time that will determine life and death for the vast majority of ARS victims of the attack—and the current plan has the American people on their own during this timeframe.

Without help during this period, the number of casualties will be staggering. According to the NNPS, “Victims will continue to absorb radiation doses while waiting on rescue and this will result in an increased likelihood of death.” Victims lucky enough to get themselves to this perimeter will be able to receive help in the form of decontamination, which will help halt further radiation damage but do nothing for the harm from the radiation already received. In other words, absent a cure for ARS, decontamination will do nothing to help those who have already been irradiated to the level that triggers ARS. For the vast majority of evacuees from the impacted area, currently planned rescue and medical efforts provided at the periphery will have little impact on mortality.

Absent first responders to assist in response efforts, the situation within the area of the blast—most likely the entire metropolitan area of one of the nation’s largest cities—will be horrific. Power will be out for some period of time. The area of outage, according to the NNPS, is likely to span several states. The NNPS further states that power will be out for a period of several days to weeks. There will be no street lights to direct evacuation traffic flows. There will be no street lamps to light evacuation routes.

Together the loss of power and the effects of the electro-magnetic pulse (EMP) will render most modern means of communication—cellphones, television, radio, blackberries, most Internet services, and even most satellite communications devices—inoperable.

Without direction, victims will be left largely in the dark about the proper courses of action. For some, the best course of action will be to shelter in place. However, such a response runs counter to normal human instinct. Without the ability to receive information from authorities, most people will leave their homes, offices and other places of shelter and seek to evacuate—in doing so they may only increase their likelihood of contracting ARS and dying.

Most food and water will be contaminated; ingesting these staples will cause further radiation injury. Depending on the timing of the attack, parents will be separated from their children, with little or no hope of reuniting during the immediate future. ATM machines will be down. Phone-dependent credit card transactions will be halted. People will have only cash-on-hand-reserves to pay for survival necessities.

Without police and military units, which will be kept out of the area do to the risk of ARS, some measure of chaos, and likely violence, is inevitable. Curfews will exist only for the truly law abiding and scared.

It may take up to two weeks before radiation in the downtown area falls below the Civil Defense “all clear” standard. Those who die from the blast will be left where they fell. The injured who cannot fend for themselves and make their own way out of the blast area will soon succumb. Bodies will litter the roadsides and rubble. Soon these corpses will begin to decompose and fester causing a wave of disease among a population that is already immune-suppressed from ARS.

Additionally, the timing of medical relief efforts under the current Strategic National Stockpile System does not fit the nuclear attack scenario. Whatever medical help we have to offer will arrive too late.

This system will not work for a nuclear attack. The deadly effects of nuclear radiation will have begun before this system can reach people with drugs. In a nuclear attack contamination will cause and require an evacuation Diaspora. Unless we reach these victims before they are spread around the nation we will have no way of catching them in time. In other words, if we let our preordained, one-size-fits-all system for distributing drugs determine our nuclear response, we will have no way to save these people.

This disconnect between plans and reality is, however, not, at base, DHS’ fault. Absent a drug to treat ARS, any realistic plan is doomed to failure. And, DHS has not been given an ARS drug to work with by HHS, which is charged with procuring such drugs.

Our nuclear response planning should focus on getting NEUMUNE out to the greatest number of victims in the fastest possible way.

How do we achieve this?

Based upon the damage ARS does and the speed at which these health impacts occur, the drug will need to be forward deployed in all high-risk areas, such as in and around major metropolitan areas, nuclear power plants, nuclear weapons facilities, nuclear waste facilities, and designated national security events. Within these areas, NEUMUNE stocks will need to be decentralized to give victims the maximum opportunity to obtain the lifesaving drug. For example, we should seriously consider pre-positioning the drug at stadiums, large malls, post offices, fire and rescue stations, police stations, hospitals, major employers, and schools and universities. Along these lines, the NNPS focuses heavily on using first responders and military units to set up decontamination stations. These units will become natural distribution points to get everything from food to blankets into the hands of vast numbers of victims and radiation refugees. It would make sense to equip these decontamination centers with NEUMUNE, which could be handed out to people as they enter the decontamination process.

Further, the forward deployment of NEUMUNE has the advantage of knowing, generally speaking, where we need to get the drug to be most effective. We not only know with some degree of certainty the most likely terrorist nuclear targets, but we also know if such an attack were to occur where we would need the drug to be available. We have the benefit of years of data about common prevailing weather conditions for most if not all of these target areas. We know what areas will most likely be downwind of an attack.

The NNPS itself notes the importance of downwind focused efforts:

Early emergency response efforts have historically been focused on lifesaving needs close to the emergency site. However, other actions need to be taken downwind where the plume will deposit radioactive fallout. Perhaps the greatest impact on saving lives will be activities immediately following the detonation that address the reduction of the future radiation dose that will be received by the population in the fallout zone immediately downwind of ground zero.

We can pre-position the drug in the likely epicenter (e.g., downtown) and in the most likely downwind regions. Beyond these commonsense initiatives, our planning processes should also consider more creative mechanisms to pre-deploy and push NEUMUNE out to the affected population. For example, in the area adjacent to ground zero, and directly downwind from the epicenter, the areas that will be hardest hit, we might use other means, perhaps even including carpet-air-drops, to get NEUMUNE into victims' hands. We should also find ways—ranging from the bully pulpit to a tax break—to encourage people, families and businesses to have their own mini-stockpiles. When DHS called upon people to purchase duct tape and plastic wrap, these goods flew off hardware stores shelves. A similar effort here could do far more to actually protect people from the nuclear threat.

Further, we cannot simply put this drug into our stockpiles and hope that people will know what to do in the event of an attack. Any effective plan to use NEUMUNE to save vast numbers of people post-nuclear attack must begin with public education. Most Americans seem to believe that it is the nuclear blast that poses the greatest likelihood of death, when in fact they are more likely to be killed by ARS. And most think you cannot possibly survive a nuclear attack, when in fact, as I have indicated, ARS can be treated and the chance for survival can be significantly increased.

These misconceptions and knowledge gaps will undermine the ability of DHS and the other response agencies to save lives with NEUMUNE. In fact, given decades of doomsday talk, I doubt the average American believes that a mere drug could help protect them from a nuclear bomb. We need to begin to educate the American people now about how this drug can save their lives and what they should do after any such attack to avail themselves of the drug and increase their likelihood of survival. For example, in most instances, if a family has NEUMUNE in the home, and if they have prepared by stockpiling food and water, and have a sheltered room in the home, that family will be better off not evacuating immediately. Rather, they should take the drug and shelter in place for a period of time to allow radiation levels to drop before seeking to evacuate. However, families aren't going to react in this way if they don't have NEUMUNE or haven't been educated about how to use it.

CONCLUSION

Imagine if we fail to act now to deploy an effective medical countermeasure to a nuclear attack. Imagine that our worst nightmare comes to pass: Osama bin Laden uses a nuclear device on American soil.

Finally, imagine the impact this attack will have on the American public as night after night, the entire rest of this nation watches in utter horror as endless news coverage captures the dying, the chaos, the ruins of the blast and the streets deserted in the wake of the fallout. The video footage will be heart wrenching. Victims left trapped under the wreckage will be seen crying for help and no help will be coming. Photographers will capture first responder units sitting on the periphery unable to go in to help. Military units, finally unable to stand these images, will disobey orders and will go in to help, only to become sick. The Pentagon will struggle with how to handle growing widespread dissension in the ranks. Television crews will track the demise of hundreds of thousands of people as ARS slowly kills them. We will hear limitless stories of families shattered, promising lives extinguished, and other boundless tragedies and ironies.

If our attackers are smart they will leave little in the way of a return address. Our political and military leadership will look impotent as they struggle with how to respond to the greatest tragedy in our nation's history—in the words of Harvard's Graham Allison, the author of the leading text on the nuclear threat, this tragedy "will make 9–11 look like a pin prick."

Commentators will appear on the network and cable news stations talking about a drug that could have saved hundreds of thousands lives had it only had been stockpiled and on hand. Talk radio will be awash with allegations of a vast conspiracy that allowed this to happen. Political leaders will call for hearings and investigations. New commissions will be formed to once again tell us that we suffered a "failure of imagination" yet again.

The failure of imagination here will not be our inability to imagine what the terrorists seek to do to the American people. We know that Osama bin Laden and al-Qa'ida are working day-in-and-day-out to attack us with a nuclear device. Bin Laden has said so himself.

Here the difficulty is in the inability to imagine how to respond to that threat. Imagine how the public will judge their leaders if, after a nuclear attack, they learn a drug was available that could have saved hundreds of thousands of lives.

How will our leaders explain why so many people died unnecessarily from a nuclear attack when there was a drug that could have saved them but their government wasn't willing to make it available to America's cities?

I ask your help today in ensuring that we look carefully at why this country remains unprepared to deal with the greatest threat facing our nation: a nuclear detonation on American soil.

Thank you for the opportunity to appear before you today

Mr. KING. And now we would recognize Mr. James A. Joyce, chairman and chief executive officer of Aethlon Medical, Incorporated. Mr. Joyce.

STATEMENT OF JAMES A. JOYCE

Mr. JOYCE. Mr. Chairman, I thank you and the committee members for the opportunity to testify today. My observations and recommendations will be based on both an entrepreneurial and scientific perspective. My name is Jim Joyce. I am the chairman and CEO of Aethlon Medical, based in San Diego, California.

Since 2001, my company has focused on developing a therapeutic device that is able to deliver the immune response of clearing pathogens and related toxins from circulation. Our technology, known as the Hemopurifier, converges the well-established principles of hemodialysis and affinity chromatography with new discoveries of affinity agents that are able to bind a wide range of envelope viruses, including many of those that are currently designated as Class A pathogens.

Our scientific efforts have been supported and guided by a world-class team of infectious disease advisers, including the former head of the Russian bioweapon program, who Congressman Weldon referenced earlier today, Dr. Alibek, and the former commander of infectious disease research at USAMRIID, which today operates as

our Nation's top facility in developing countermeasures against biological weapons.

We believe that our Hemopurifier will serve as an effective adjunctive therapy when treatment options do exist, and most importantly the Hemopurifier is available today as the first line of defense against drug-and vaccine-resistant bioweapons, including pathogens that have been genetically engineered for virulence and treatment resistance.

I should reference that the concept of extracorporeal devices to filter or clear pathogens is not novel. Hemofiltration was utilized in the Soviet Union in 1990 to save a bioweapon researcher from late-stage Marburg infection. This is published in scientific journals. Leroy Richmond, a postal worker infected with anthrax in the attacks of 2001, attributes the difference between his survival and the death of two coworkers as being a series of plasmapheresis procedures he received to combat anthrax toxins. Today, hemofiltration has evolved to be a common therapy in treating sepsis and septic shock, which is the primary cause or cause of death in most viral conditions, including conditions related to biological weapons.

Now that I have provided the committee with background information, I wish to proceed with two comments related to current BioShield legislation. Number one, further clarification in the definition of "countermeasure." New legislation expands the definition of countermeasure to include the general term "therapeutics," but does not reference therapeutic devices specifically. In our pursuit of research grants with the NIH, we have found that the general term "therapeutic" for viral infection is traditionally considered by examiners to mean a drug or vaccine. In this regard, the definition of "countermeasures" should specify and include therapeutic devices that reduce viral load or modulate cytokine production.

Number two, presence of nonbioweapons markets. Early versions of Project BioShield would have eliminated the consideration of a stockpile purchase if other significant markets existed for a countermeasure. Such language has since been revised to require the presence of another commercial market must be factored into the HHS Secretary's decision to purchase a potential countermeasure.

I believe that such open-ended language will deter organizations from pursuing development of innovative therapies against biowarfare agents. This language is also counterintuitive as the best hope for treating such a wide range of threats is through the evolution of postexposure immunotherapeutic countermeasures, especially when considering the added challenge of combating pathogens that have been genetically modified.

Therapies that are able to augment the immune function or modulate cytokine production are going to have large market opportunities beyond the treatment of bioweapons. If developed, these therapies will globally impact the treatment of other infectious disease, including established pandemics such as HIV and AIDS, and new evolving pathogens such as avian flu virus.

BioShield legislation should be embraced because of these possibilities. If the goal is to attract the development of treatment countermeasures, then references that imply the presence of a broader market as being potentially detrimental should be eliminated.

In the case of Aethlon Medical, we are preparing to initiate human trials to treat HIV and hepatitis C. We do not have the luxury of betting the life of our company on the hope that BioShield legislation will be inclusive of our technology. In that case, we would like to think that science itself will drive the value of new technologies into the marketplace. Thank you for your time.

Mr. KING. Thank you, Mr. Joyce.

[The statement of Mr. Joyce follows:]

PREPARED STATEMENT OF JAMES A. JOYCE

Mr. Chairman, I thank you and the Committee Members for the opportunity to testify. The observations and recommendations I provide today are derived from both an entrepreneurial and scientific perspective. I am the Chairman, and CEO of Aethlon Medical, Inc., based in San Diego, California. Since 2001, my Company has focused on developing a therapeutic device able to deliver the immune response of clearing pathogens and related toxins from circulation. Our technology, known as the Hemopurifier™ converges the established principals of hemodialysis and affinity chromatography, with the recent discovery of affinity agents that are able to bind a broad spectrum of envelope viruses, including those that have been classified as bioterror threats.

Our scientific efforts have been supported and guided by a world-class team of infectious disease advisors, including the former head of the Russian Bioweapon Program, and the former Commander of Infectious Disease Research at USAMRIID, which today operates as our Nation's premier bioweapon research institute. We believe that the Hemopurifier will serve as an effective adjunctive therapy when treatment options exist, and most importantly, the Hemopurifier is available today as a first line of defense against drug and vaccine resistant bioweapons. This includes pathogens that have been genetically engineered for virulence and treatment resistance.

I should reference that the utilization of extracorporeal devices to filter or clear pathogens is not a novel concept. Hemofiltration was utilized in the Soviet Union in 1990 to save a bioweapon researcher from late stage Marburg infection. Leroy Richmond, a postal worker infected with Anthrax in the attacks of 2001, attributes the difference between his survival and the death of two co-workers as being a series of plasmapheresis procedures he received to combat circulating anthrax toxins. Today, Hemofiltration has evolved to be a common therapeutic intervention for the treatment of sepsis and septic shock, which is often the primary cause of death in viral infection.

Now that I have provided the Committee with background information, I wish to proceed with two comments related to current BioShield legislation.

1. Further Clarification in the Definition of Countermeasure—New BioShield legislation expands the definition of countermeasure to include the general term “therapeutics” but does not reference therapeutic devices specifically. In our pursuit of research grants at the NIH, we have found that the general term “therapeutic” for viral infection is traditionally considered by examiners to mean a drug or vaccine. In this regard, the definition of countermeasure should specify and include; “therapeutic devices that reduce viral load or modulate cytokine production”.

2. Presence of Non-Bioweapon Markets—Early versions of Project BioShield would have eliminated the consideration of a stockpile purchase if other significant markets existed for a countermeasure. Such language has since been revised to require that the presence of another commercial market must be factored into the HHS Secretary's decision to purchase a potential countermeasure. I believe that such open-ended language may deter organizations from pursuing the development of innovative therapies against biowarfare agents. This language is also counter intuitive as the best hope for treating such a wide range of threats is through the evolution of post-exposure immunotherapeutic countermeasures. Especially when considering the added challenge of combating pathogens that have been genetically modified. Therapies that are able to augment the immune function or modulate cytokine production are going to have large market opportunities beyond the treatment of bioweapons. If developed, these therapies would globally impact the treatment of infectious disease, including established pandemics such as HIV/AIDS, and new naturally evolving viral conditions. BioShield legislation should be embraced because of these possibilities. If the goal is to attract the development of treatment countermeasures, then references that imply the presence of a broader market as being potentially detrimental should be eliminated. In the case of Aethlon Medical, we are

preparing to initiate human trials to treat HIV and Hepatitis-C. We do not have the luxury of betting the life of our Company on the hope that BioShield legislation will be inclusive of our treatment technology. As the same time, our pursuit of other treatment markets should have no bearing as to whether our technology is stockpiled as a countermeasure against biowarfare agents. The stockpiling of our Hemopurifier should be based solely on its ability to save the lives of citizens exposed to biowarfare agents.

In closing, I thank you again for the opportunity to testify. Bioterrorism is clearly one of the most dangerous threats facing our nation, and I commended the committee members for devoting attention to this problem. I would now be pleased to address any questions you may have.

Mr. KING. And the Chair now recognizes the president of-Ms. Nancy Wysenski, the president of EMD Pharmaceuticals.

Excuse me, Mr. Wright, I am sorry, we will come back to you, sir.

STATEMENT OF NANCY J. WYSENSKI

Ms. WYSENSKI. Thank you. Chairman King, Congressman Pascrell, members of the committee, thank you for the opportunity to appear before you today. My name is Nancy Wysenski. I am the president of EMD Pharmaceuticals, located in Durham, North Carolina. EMD is a research and development pharmaceutical company specializing in the areas of neurodegenerative diseases, oncology, and cardiometabolic care. Our parent company is also the global provider of Cyanokit, a cyanide antidote kit designed specifically to be used as an immediate field antidote against large-scale cyanide poisoning, whether resulting from chemical terrorism, industrial accidents, or due to smoke inhalation. This promising technology has the potential to provide dual-use protection. It has the potential benefits not only for responding to terrorist incidents, but also to everyday emergencies where our first responders and others fall victim to smoke inhalation every day.

EMD's Cyanokit is precisely the type of countermeasure the government should be considering for broad deployment to both the strategic national stockpile and first responders throughout the country. EMD, a subsidiary of Merck, KGaA, is currently working with the Food and Drug Administration to register this product in the United States. Indeed, the FDA's Division of Counterterrorism has shown significant interest in our development plan to obtain U.S. marketing approval. Clinical trials are in progress for the use of hydroxocobalamin, the chemical name for the compound comprising Cyanokit, encountering what we believe should be one of the most concerning chemical threats facing Homeland Security, cyanide poisoning.

Cyanide is one of the most prevalent industrial chemicals in use today in the United States. It is also one of the most deadly chemicals in the environment. Nearly 100,000 tons are produced by various industries in the United States annually, with most of it shipped via our inter-modal transportation system, rails, highways, waterways, et cetera.

Cyanide is one of the deadliest and most widely available potential agents for use by terrorists as identified by U.S. intelligence sources. In public documents released by the Central Intelligence Agency on the potential threat of chemical, biological, radiological, and nuclear attacks to the U.S., cyanide is listed as the leading potential chemical agent of choice by terrorist groups. Specifically, the

CIA cites that Cyanokit can cause—excuse me. Exposure to cyanide can cause nausea, vomiting, palpitations, confusion, hyperventilation, anxiety, and vertigo, which eventually progress to agitation, stupor, coma, and death. At high doses, cyanide causes immediate collapse.

The reality of the current state of preparedness for meeting the threat of cyanide poisoning in the United States is disheartening. In 2001, prior to the incidents of 9/11, a medical expert quoted, “The United States is under the constant threat of a mass casualty cyanide disaster from industrial accidents, hazardous material transportation incidents, and deliberated terrorist attacks. The current readiness for cyanide disaster by the emergency medical system in the United States is abysmal. We as a Nation are simply not prepared for a significant cyanide-related event.”

During the legislative process that led to the passage of Project BioShield, both the House Committees on Government Reform and Energy and Commerce directed that provisions should be made to address the threat of cyanide poisoning under the supervision of the Department of Homeland Security. EMD did nothing to lobby for this report language. In fact, it was only brought to our attention by our outside counsel in 2004 when we stepped up our efforts for greater outreach to policymakers in Washington, D.C. Thus, it appears that the Federal Government, not industry, made Congress aware of the potential benefits of hydroxocobalamin to treat cyanide and the need to purchase this important countermeasure under Project BioShield.

Once approved for use in the U.S., or even prior to final FDA approval under IND status or emergency use authorization provisions afforded by Project BioShield, hydroxocobalamin can be stockpiled and then administered on site at the scene of a chemical terrorism disaster, providing immediate aid to victims. The only currently licensed cyanide kit generally requires transport to a local hospital and further is cumbersome to administer, consisting of not just one component, but three.

Most importantly, the current antidote cannot be used for victims of smoke inhalation; it may worsen their medical condition. However, Cyanokit is available for use in this manner, and according to the current implementation of Project BioShield by the Departments of Homeland Security and Health and Human Services, DHS must first determine that cyanide is a material threat by conducting a material threat assessment.

To date, the Secretary of DHS has issued material threat determinations, as we have heard today, for four agents. In our quest for an answer, EMD became aware that a material threat assessment had not been conducted for analyzing the cyanide threat, and therefore HHS had no grounds for dictating the need for a medical countermeasure against cyanide.

Mr. McCAUL. [Presiding.] Ms. Wysenski, I would ask that you try to wrap up your testimony. Thank you.

Ms. WYSENSKI. Okay. In conclusion, the need is clear that more must be done to address the threat of a terrorist-created cyanide poisoning event. The international community is acutely aware of just how quickly terrorist organizations are recognizing cyanide poisoning as a leading method for inflicting mass casualties. In-

deed, the Governments of both France and Italy have not only recognized the substantial risks of this threat, but have recently stockpiled significant quantities of Cyanokit to better prepare their communities for responses to these threats.

In conclusion, I would suggest that, given the most recent and graphic terrorist attacks that have been perpetrated in Europe, it is even more important to assess whether we are adequately prepared. This will require much more aggressive focus on material threat assessments, a transparent relationship between DHS and private industry, and, lastly, a purchase agreement must be clear to incent industry to bring products from R&D to our citizens.

Mr. McCAUL. Thank you, Ms. Wysenski.

[The statement of Ms. Wysenski follows:]

PREPARED STATEMENT OF NANCY WYSENSKI

Chairman King, Congressman Pascrell, members of the committee, thank you for the opportunity to appear before you on this critically important subject of Project BioShield and chemical, biological, radiological, and nuclear medical countermeasures. My name is Nancy Wysenski and I am the President of EMD Pharmaceuticals, located in Durham, North Carolina. EMD is a research and technology company specializing in the areas of neurodegenerative diseases, oncology and cardio metabolic care. Our parent company is also the global provider of Cyanokit, a cyanide antidote kit designed specifically to be used as an immediate field antidote against large scale cyanide poisoning whether resulting from chemical terrorism, industrial accidents, or due to smoke inhalation. This promising technology has the potential to provide dual use protection—it has potential benefits not only for responding to terrorist incidents, but also, to everyday emergencies where first responders and others fall victim to smoke-inhalation every day. EMD's Cyanokit is precisely the type of countermeasure the government should be considering for broad deployment to both the Strategic National Stockpile and first responders throughout the country.

EMD, a subsidiary of Merck, KGaA, is currently working with the Food and Drug Administration to register this product in the United States. Indeed, the FDA's Division of Counter-Terrorism has shown significant interest in our development plan to obtain US marketing approval. Clinical trials are in progress for the use of *hydroxocobalamin*, the chemical name for the compound comprising Cyanokit, in countering what we believe should be one of the most concerning chemical threats facing Homeland Security: cyanide poisoning.

The Threat:

Mr. Chairman, cyanide is one of the most prevalent industrial chemicals in use today in the United States. It is also one of the most deadly chemicals in the environment. Nearly 100,000 tons are produced by various industries in the United States annually, with most of it shipped via our inter-modal transportation system; including rail, highway and waterway transportation systems. Cyanide also remains one of the deadliest—and most widely available potential agents for use by terrorists as identified by U.S. intelligence sources.

In public documents released by the Central Intelligence Agency (CIA) on the potential threat of Chemical, Biological, Radiological and Nuclear attacks (CBRN) to the U.S., cyanide is listed as the leading potential chemical agent of choice by terrorist groups. The relative ease of access and plentiful supply make cyanide a particularly attractive method for inflicting large scale harm to the general population. Specifically, the CIA cites the following rationale as to why much greater concern should be given regarding the potential use of cyanide by terrorist groups:

“several groups of Mujahidin associated with al-Qa’ida have attempted to carry out “poison plot” attacks in Europe with easily produced chemicals and toxins best suited to assassination and small-scale scenarios. These agents could cause hundreds of casualties and widespread panic if used in multiple simultaneous attacks. . . Exposure to cyanide may produce nausea, vomiting, palpitations, confusion, hyperventilation, anxiety, and vertigo that may progress to agitation, stupor, coma, and death. At high doses, cyanides cause immediate collapse.”¹

¹ CIA, “Terrorist CBRN: Materials and Effects”. September 2003.

I thank you for your time and I would welcome your questions.

The most important point to be drawn from the CIA's analysis is the need to have immediate and adequate quantities of antidotes made available in the field prior to the emergency or attack to provide the greatest chance of survival.

However, the reality of the current state of preparedness for meeting the threat of cyanide poisoning is disheartening. In 2001, medical experts viewed the ability of the United States to respond to a terrorist incident involving cyanide with a high degree of angst:

"The United States is under the constant threat of a mass casualty cyanide disaster from industrial accidents, hazardous material transportation incidents, and deliberated terrorists attacks. The current readiness for cyanide disaster by the emergency medical system in the United States is abysmal. We, as a nation, are simply not prepared for a significant cyanide-related event."²

This comment came from a publication prior to 9/11, and unfortunately, in the last four years, nothing has changed.

With the passage of Project BioShield, the Department of Homeland Security in conjunction with the Department of Health and Human Services now has the mechanism at hand that can greatly increase U.S. emergency medical preparedness for a cyanide disaster. They will not meet that goal, however, without increased involvement by industry and a demonstrated willingness for the government to push forward with the implementation of Project BioShield in the way Congress intended.

The Challenge:

During the legislative process that led to the passage of Project BioShield, both the House Committees on Government Reform, and Energy and Commerce directed that provisions should be made to address the threat of cyanide poisoning under the supervision of the Department of Homeland Security:

"...under the authority provided by the bill, the government could procure countermeasures against chemical agents (nerve, blister, blood, and pulmonary agents) and radiological and nuclear agents. The Administration currently does not plan to use the bill's authority to purchase agents that could mitigate threats from these sources, but it could do so if the perceived threat from these agents changed or if certain treatments became scientifically feasible. Countermeasures that could be acquired under Project BioShield include existing treatments for many nerve gases (including VX, Sarin, and Soman gas), Prussian Blue (a treatment for certain types of radiation poisoning), and hydroxocobalamin (a treatment for cyanide poisoning that is in an advanced stage of development)."

EMD did nothing to lobby for this report language. In fact, it was only brought to our attention by our outside counsel in 2004 when we stepped up our efforts for greater outreach to policymakers in Washington D.C. Thus, it appears that the Federal Government—not industry—made Congress aware of the potential benefits of hydroxocobalamin to treat cyanide and the need to purchase this important countermeasure under Project BioShield.

Hydroxocobalamin is being developed as an antidote for treatment of cyanide poisoning due to smoke inhalation, chemical terrorism, or industrial exposure. As previously stated, the product is already registered by EMD's French affiliate, Merck Sante as a cyanide antidote under the international brand name *Cyanokit*, and currently is stocked on fire trucks and ambulances for first responder use in France where it has been in use for over 8 years.

Once approved for use in the U.S., or even prior to final FDA approval under IND status or Emergency Use Authorization provisions afforded by Project BioShield, hydroxocobalamin can be stockpiled and then administered on-site, at the scene of a chemical terrorism disaster, providing immediate aide to victims. The only currently licensed cyanide kit generally requires transport to a local hospital and, further, is cumbersome to administer, consisting of not just one component but three. More importantly, the current antidote cannot be used for victims for smoke inhalation, because it may actually worsen their medical condition. However, before hydroxocobalamin or Cyanokit is available for use in this manner, and according to the current implementation of Project BioShield by the Departments of Homeland Security and Health and Human Services (DHS and HHS, respectively), DHS must determine that cyanide is a material threat by conducting a Material Threat Assessment (MTA). Even though during the first days in Afghanistan in 2001, our military seized videotapes from terrorist training camps showing al-Qa'ida experimenting

² Sauer SW, Kein ME. *Hydroxocobalamin: improved public health readiness for cyanide disasters*. Annals of Emergency Medicine. June 2001; 37: 635–641

with cyanide by poisoning dogs, it is our understanding that, as of yet, no MTA is underway or planned.

Within DHS, the Directorates for Information Analysis and Infrastructure Protection (IAIP) and Science & Technology (S&T) work together in conducting assessments and determinations of biological, chemical, radiological and nuclear agents of greatest concern so as to guide near-term BioShield requirements and acquisitions. Plausible high consequence scenarios that provide an indication of the number of exposed individuals, the geographical extent of the exposure, and other collateral effects are drafted. If these consequences are of such a magnitude to be of significant concern to our national security or public health, the Secretary of DHS then issues a formal Material Threat Determination to the Secretary of HHS, which initiates the BioShield process.

To date, the Secretary of DHS has issued Material Threat Determinations for four agents: anthrax, smallpox, botulinum toxin, and radiological/nuclear devices. DHS tells us that additional threat assessments are underway for the remaining Category A biological agents as identified by the Centers for Disease Control and Prevention (plague, tularemia, viral hemorrhagic fevers) and for nerve agents. In our quest for answers, EMD became aware that an MTA had not been conducted for analyzing the cyanide threat and therefore HHS had no grounds for dictating the need for a medical countermeasure against cyanide. Disconcertingly, there appeared to be confusion among the DHS staff as to who would actually conduct the MTA. It is surprising that, to our knowledge, DHS has not addressed the threat of toxic industrial chemicals, such as cyanide, considering the high level recognition of the threat posed by such chemicals.

EMD's status in the BioShield procurement process has been stalled in the very first phase of the Material Threat Determination. For over a year EMD has been seeking answers to questions that clearly have an impact on critical business decisions. Without the MTA from DHS, HHS understandably is not armed with the information necessary to address our questions. We have no indication if the government will buy Cyanokit, when it will buy it, or how much it will buy. Without the MTA, we don't even know if Cyanokit will fit the operational profile of the countermeasure that is called for to meet cyanide countermeasure needs or if it could be adapted to meet those needs. Without such answers, answers that will be informed by the results of an MTA on cyanide, EMD cannot adequately plan for production and facility expansion, and makes us question whether to proceed with product development at our company's expense in making Cyanokit available to the USG. Without a change in that status, the country is not likely to receive the benefit of protection against this looming threat.

The need is clear that more must be done to address the threat of a terrorist created cyanide poisoning event. The international community is acutely aware of just how quickly terrorist organizations are recognizing cyanide poisoning as a leading method for inflicting mass casualties. Without adequate countermeasures in place, on the ground, stockpiled for use in time of emergency, most if not all victims will succumb to the effects of cyanide poisoning. However, without greater cooperation between industry and the government and, most importantly, greater transparency from the Federal government on how Project BioShield is being implemented, companies with the resources and capabilities of EMD will simply not be able to sustain viable interest in this market. The nation, and in fact, the world, cannot afford this risk.

Indeed, the governments of both France and Italy have not only recognized the substantial risks of this threat, but have recently stockpiled significant quantities of Cyanokit to be better prepared in responding to this threat.

In conclusion, I would suggest that given the most recent and graphic terrorist attacks that have been perpetrated in Europe, it is even more important to assess whether we are adequately prepared to deal with the additional threat of a lethal release of cyanide in such a circumstance. The events in Tokyo in 1990's starkly bear this fact out.

If we are to address the threat of cyanide poisoning in the United States, we must move forward with the implementation of Project BioShield as Congress and the President intended. First and foremost, Material Threat Assessments should be completed on all perceived threats. Furthermore, industry needs increased transparency of the BioShield process and feedback from the government to keep us engaged in bio-chem defense efforts and be able to provide the government and public with urgently needed medicines. Enhanced communication and teamwork between DHS and HHS and industry will greatly aid EMD and other companies to bring products from R&D to market for the purpose of defending our Nation against chemical, biological, radiological, and nuclear attacks.

I thank you for your time and I would welcome your questions.

Mr. McCAUL. The Chair now recognizes David Wright, the CEO of PharmAthene, Inc., for 5 minutes.

STATEMENT OF DAVID P. WRIGHT

Mr. WRIGHT. Mr. Chairman, members of the committee, PharmAthene was founded to develop countermeasures for bioterrorism. In 2 short years we have brought two products forward to a stage where the national strategic stockpile could soon acquire them. PharmAthene has had experience with Project BioShield, DHHS, DOD, DHS in developing our products Valortim, an anthrax therapeutic, and Protexia, a chemical bioscavenger against nerve agents.

DHS plays a critical role in determining what constitutes a material threat and what the scope of that threat is. Today I would like to discuss how the material threat analysis and requirements, products, processes affect biodefense companies like mine. Three critical issues I would like to highlight are: Number one, transparency, identifying the government's countermeasure needs early enough for companies to make informed decisions; two, the requirements process, creating a more coordinated streamlined and timely process; and, three, BioShield funding, ensuring adequate funds are made available to support the Nation's biological and chemical defense needs.

The Project BioShield procurement process should be more transparent. I believe Department officials should develop ways to integrate industry into countermeasure decisionmaking sooner. DOD, which has considerable experience in developing complex weapons systems that have no other commercial market, is a good case study. DOD identifies future capacity needs early on and fully funds these programs. For instance, several times a year DOD officials meet with industry to outline their needs and seek partners.

Mr. WRIGHT. Once a promising technology is identified, funding is available to support complete product development, from proof of concept, through the actual acquisition. We contend that Project BioShield would attract more interest and investment from industry if it employed similar techniques.

The second issue, the requirement process, much can be done to expedite the process and better communicate the results. The current process is too complicated and disjointed. DHS, HHS and many other agencies and departments, including DOD, OMB and the Intelligence Community, are involved in decisionmaking. With so many chefs in the kitchen, it is unclear who or which department or which agency has the ultimate decisionmaking authority. Moreover, the time needed to reach an agreement is substantially lengthened.

Another issue involves a link between the original threat analysis and the actual strategic stockpile requirement.

Last year PharmAthene responded to an RFP that requested bids to provide from 10,000 to 200,000 anthrax treatments. 10,000 or even 20,000 treatments is not a market any company can afford to consider. Furthermore, the cost to the U.S. government would be prohibitive on a per dose basis.

If the MTA indicates only a very limited exposure that leads to a small strategic national stockpile requirement, companies need

this information up front to evaluate the program opportunities and make informed decisions. We propose that your committee consider mechanisms to both streamline the requirement process and communicate early and clearly the government's procurement intentions.

Lastly, Congress has taken an important first step to combat biological and chemical terrorism by setting aside 5.6 billion. Unfortunately, it is insufficient to support the breadth of technology's needed to protect this Nation. Because of this we are troubled by the prospect that MTAs may, in some instance, be based on unrealistic scenarios to meet a certain fiscal end.

To be effective, MTA would should into account not only the likely exposure estimate, but also the long-term effects of biological or chemical attack. Threat analysis should not be limited to what can be accomplished with current funding but should be devised separately from fiscal constraints.

I am convinced that BioShield II can be a powerful incentive to companies in the biodefense sector, and I urge you to include provisions to enhance transparency, streamline the requirement process and authorize additional funds as necessary.

Thank you.

[The statement of Mr. Wright follows:]

PREPARED STATEMENT OF DAVID P. WRIGHT

Mr. Chairman, Members of the Committee: I commend this committee for its focus on the vital legislation which brings us together today.

I am David Wright, President and CEO of PharmAthene.

PharmAthene was founded to develop countermeasures for bioterrorism and has made significant progress in developing products which prevent and treat anthrax and agents of chemical warfare. In two short years, we have brought two products forward to a stage where they could soon be acquired for the Strategic National Stockpile.

PharmAthene has had experience with Project BioShield, DHHS, DOD, and indirectly DHS in developing our products. Our lead product, Valortim™, which we are co-developing with Medarex based in New Jersey, has demonstrated significant efficacy in preventing and treating anthrax and is poised to become an important component of the U.S arsenal to combat this dire threat. Our second product, Protexia™, an effective countermeasure against chemical and nerve agents, has gained critical support from DOD, which has a strong interest in developing and procuring effective nerve agent antidotes to protect the war fighter. PharmAthene has invested in these technologies because the USG clearly communicated it was seeking effective countermeasures in the anthrax and chemical areas.

As a company devoted to the area of biological and chemical defense we have made a great start in a short amount of time. However, it is difficult to determine where we should go next, or to substantiate potential acquisitions or investments to my board, because the current procurement process is cumbersome from two principal vantage points: (1) it is not transparent and (2) it does not provide sufficient information about future countermeasure needs. It costs over \$150 million to bring a new biodefense drug to the market and a typical drug development program takes 4-6 years. Companies, particularly small biotechnology companies like PharmAthene, cannot afford to make these types of investments unless they believe there is a real and sustainable market for their products.

DHS plays a critical role in determining what constitutes a material threat and what the scope of that threat is. It is this role, and how the material threat assessment (MTA) process, which culminates in an actual requirement for SNS procurement, affects biodefense companies like mine, that I would like to discuss this morning. These include:

- (1) Transparency—identifying the government's countermeasure needs early enough for companies to make informed decisions
- (2) The Requirements Process—creating a more coordinated, less burdensome, and timely requirements process, and

(3) BioShield Funding—ensuring adequate funds are made available to support the nation's biological and chemical defense needs

In order to be successful, the Project BioShield procurement process must be more transparent. I believe Department officials and industry must work together to develop ways to integrate industry into countermeasure decision making sooner. The DOD process is a good one to review here, as DOD has a lot of experience developing complex weapons systems and involving industry early. Our Protexia product has certainly benefited from the DOD approach. DOD identifies capability needs for the near-term, mid-term and long-term and fully funds these programs. These capability needs are shared with industry and several times a year, DOD officials meet with industry to outline their needs and seek partners. Further, once a promising technology is identified, funding is available to support development across the complete development spectrum through the tech base, Milestone A and Milestone B process. Project BioShield would attract more interest and investment from industry if it employed similar techniques.

With regard to the requirements process, much can be done to expedite the process and better communicate the results. The current process is complicated and disjointed. Before DHHS can actually procure a countermeasure for stockpile, a number of activities must occur—DHS must complete an MTA, which can take from several months to several years, DHHS must determine there is a need for new countermeasures, and the many members of the Weapons of Mass Destruction—Medical Countermeasures group must agree on a requirement. In addition, to DHS and DHHS, many other agencies and Departments are involved in this process including DOD, OMB, and the intelligence community. It is unclear who or which department or agency has ultimate decision making authority. Plus, with so many chefs in the kitchen the time needed to reach agreement is substantially lengthened delaying procurement decisions.

A second issue is, what appears to be, a tenuous link between the original threats analysis and the actual SNS requirement. Last year, PharmAthene responded to an RFP that requested offerors to bid on providing anywhere from 10,000 treatments to 200,000 treatments. Ten thousand treatments or even 20,000 treatments are not a market any company can afford to consider. It is not reasonable to expect companies to invest millions of dollars in a technology for such a small order. If the original MTA indicated only a very limited exposure resulting in a limited SNS requirement, companies need this information up front to evaluate program opportunities and inform decision making. Furthermore, the cost to the U.S. government would be prohibitive on a per dose basis. If, on the other hand, a much larger requirement is warranted based on the MTA and DHHS assessments, but the resulting RFP does not reflect the real need, there is a disconnect in the requirements process. We would hope that given the importance of developing countermeasures to protect the nation, that as part of your deliberations on BioShield II, the committee would consider mechanisms to both streamline the requirements process and communicate early and clearly the government's procurement intentions (what, when, how much).

Finally, I would like to note one other issue that we believe is critical in your consideration of BioShield II—funding. Congress has taken the first step in combating biological and chemical terrorism by setting aside \$5.6 billion for SNS procurement. This is a good first step. Yet it is insufficient to support the breadth of technologies needed to protect this nation. To be effective, MTAs should take into account not only the likely exposure estimate but also the long-term effects of a biological or chemical attack. A realistic anthrax scenario, for example, must address not only the morbidity and mortality of the exposed population, but also take into account how the geographic area will be impacted. Anthrax can exist in the soil for over 30 years. The resources necessary to make the area inhabitable again will be enormous. Threat analyses should not be limited to what can be accomplished with current funding, but should be devised separately from fiscal constraints. While industry recognizes that funds in this area are not limitless, a process that begins with estimates based on unrealistic scenarios or developed to meet a certain fiscal end, will not only discourage companies from entering this market, but also leave our country woefully unprotected.

Thank you for the opportunity to share my views on BioShield II with you today. I believe BioShield II can be a powerful incentive to companies in the biodefense space, and urge you to include important provisions enhancing transparency, streamlining the requirements process and authorizing additional funds as necessary. Doing so, will go a long way toward ensuring that the USG can procure the products it needs to protect the American people.

I would be pleased to address any questions the Committee may have at this time. Thank you.

Mr. MCCAUL. Thank you, Mr. Wright. The Chair recognizes himself for 5 minutes for questions.

I mentioned to the previous panel I am reading "1776" by David McCullough. He talks about how the British were using their weapon of choice beginning at the Revolutionary War. They were looking at something called smallpox and infiltrating our troops in an attempt to wipe out the enemy. So it is nothing new in our history. It is something that we need to remain vigilant and focused on.

I am very interested in the public and private partnerships in all areas of the government. This is clearly one where there is a great need for that. What I am concerned about, though, is that the biggest pharmaceutical companies—and I appreciate the ones who are here, the smaller companies—but the biggest companies are not interested in participating in BioShield.

I wanted to see if you could tell me what impact you believe that is making on our homeland security and what, if anything, the Federal Government could do to bring them to the table so they can be full participants in protecting our national security.

Mr. HOLLIS. I will try to answer that. I don't really think it makes a difference whether it is a big pharma or small biotech. I think the bottom line to it is industry needs to understand what this biodefense industry really is. The threats need to be identified, and the size and scope of the markets, so we can determine whether our technology is worth developing for that particular medical countermeasure.

I think the reason that a lot of small companies are looking at this is because they are the ones that are really pushing the envelope on new cutting edge technology.

Big pharma licenses a lot of its products from small biotech companies. So I don't know if it is big versus small. I think it is just the biodefense sector in general is really not really excitable by the capital markets. The capital markets are not responding, because they don't believe that the government is totally committed to this. If the capital markets were interested, believe me, so would big pharma.

Mr. MCCAUL. Any other comments?

Dr. CARR. If I could add a little bit to that. One of the problems that was raised earlier in the first panel was about the procurement precluding to a certain degree the products that already had significant commercial markets. And although we were told that that was not an absolute preclusion, it certainly is a preclusion. I think that is one thing that would deter a large company from being involved. Also, the fact that several people have addressed, in terms of the process, of the material threat assessment followed by a specific response to that and a call for grants is very protracted and really precludes responses that might be already inherent in some drugs that have been developed by large pharma companies and have not been looked at for potential in applications in these areas.

I think if the process could be allowed to let them look at some of these other indications, you would have drugs that are already FDA approved for other indications that might come into application.

Mr. GREENBERGER. I would just use one word, indemnification. That is, everywhere you look, phase 1 smallpox program, where the President wanted 500,000 first responders vaccinated, 40,000 ended up being vaccinated. A survey was done, indemnification. Be very careful.

I know that BioShield II is talking about indemnification and people want to grab old statutes and say well, here is indemnification. They tried to do that, Congress passed a law in April of 2003 to indemnify. Not good enough.

You have to look at this very carefully. If the government needs to be a deep pocket in this regard, it is well worth it to get these vaccines on the market.

Mr. JOYCE. Mr. Chairman, I would add one other comment. I was privileged to be involved in a gathering of bioindustry thought leaders yesterday afternoon. I think there was one common, and that is therapeutic innovation occurs at small companies. The challenges we have today are challenges of efficiency and clarity in the system.

Another conclusion is that small companies do not have experience in navigating through systems that seem to be developed for companies of the magnitude of Northrop Grumman and other large biodefense or other large defense contractors. So there needs to be greater clarity and efficiency of systems.

The other thing that was a conclusion or a concern is that a lot of the decisions being made regarding what pathogens are actual threats are being made by individuals that don't actually have experience in dealing with these pathogens. That is a very large concern, and it goes back to the material threat assessment issues.

There are people available that do have experience in dealing with these pathogens, and there has been a lot of academic pontification regarding what is and what isn't a threat. I think in many cases those thoughts are not the same thoughts of people that have experience with dealing with these pathogens.

Thank you.

Mr. MCCAUL. Ms. Wysenski.

Ms. WYSENSKI. If I could add again, the need to expedite the process so that we can see a far higher number of material threat assessments being done. That is the only way that private industry, small or large, knows that they will have a market to address. Most companies are making trade-off decisions between investment opportunities. If it isn't clear what the process is, that a material threat assessment will be done, which will likely lead to a market demand, companies will be swayed to make their investments in other areas.

Mr. MCCAUL. I thank you. I see my time has expired. The Chair now recognizes the ranking member, Mr. Pascrell, for 5 minutes.

Mr. PASCRELL. Thank you. There seems to be agreement that pharmaceutical companies are hesitant to take part in the BioShield program due to the potential for liability, the low or uncertain demand even if products are developed, and the potential that companies would lose intellectual property rights if the government allowed others to produce the product during an emergency. I think that these concerns are reasonable.

I want you to rank these issues quickly.

Should the Congress address these concerns? How should they address those concerns? Why don't we start with

Mr. Hollis, as quickly as you can?

Mr. HOLLIS. Well, sure the liability issues are important because pharmaceutical companies have a lot to lose. They are targets for lawsuits. I believe that the experience that we had with other products when the anthrax attack first happened, I think it was the Secretary who was looking to basically bypass that pharmaceutical company's patents because of a public health emergency.

So I think patents are extremely important, and there should be protection under the legislation that if you are developing a medical countermeasure against WMD that those patents should be honored.

Mr. GREENBERGER. I think liability definitely needs to be dealt with in legislation. Congress has tried to do this most recently with the SEPA Act in 2003 dealing with smallpox. Both manufacturers, medical providers, unions who represent first responders that are worried about compensation were uniformly unhappy with that.

I think the government is going to have to spend a lot of money in this area a very small portion of it would be to tell big pharma, who is really worried about liability, because they have so much at stake.

And conversely, the first responders, who have to be vaccinated pre-event, don't worry, will step in. This is so important the government will be a deep pocket, and we will take care of things. Now, that may sound shocking, but the cost of doing that pales against the amounts of money that are being spent on other efforts.

With regard to patents, you have got to be very careful, what happened in anthrax. I mean, we have these very high drug prices. And if somebody who holds a patent is going to stand in the way of making affordable and easy distribution in an emergency, reassuring the strength of that patent may not be the wisest course in an emergency. It is a very tricky issue, but it deserves the attention of Congress, and it can be solved legislatively.

Mr. MCCAUL. Anybody else?

Mr. JOYCE. Yes, I would make one comment as a rebuttal and it would refer back to what we heard from the Assistant Secretary of HHS today. Educated that they had allocated \$88 million towards a certain countermeasure issue, the reality is that the average drug, the cost of developing the average drug today is about \$800 million and takes about 10 years. If you look at the development process of drugs and vaccines, only a very minute percentage of those compounds that even go into trials ever are proven to be safe and effective.

So there is a major disconnect between the dollars being spent and the dollars required to develop new therapeutics.

Mr. PASCRELL. Anyone else?

Dr. CARR. I would just emphasize once again the liability issue. I think that goes across the board, because a large company with a deep pocket, there is grave concern. But also for a small, could be wiped out in these same situations.

Mr. PASCRELL. You know, Dr. Greenberger, right, I read your testimony quickly. I find it pretty astonishing in terms of what else we have heard today and the questions from both sides.

You say on page 3 of your testimony that the BioShield Act established no procedure for DHS to employ and supervise the making of material threat determinations. That is interesting and true.

Despite what was an obvious Congressional invitation to summarize determine what are the widely-priced CBRN threats to the United States, DHS has employed an opaque, highly-bureaucratized relatively lengthy process for determining material threats. Congressmen—you say poorly-delineated administrative strengths. Do you really mean what you said?

Mr. GREENBERGER. Oh, absolutely. I am absolutely confident that when Congress assigned DHS the responsibilities of outlining material threats that they thought that that was going to be a very easy and quickly done task. I mean, the testimony here today, Chairman King, opened up Marburg and Ebola. Who would argue about Marburg and Ebola? Yet that isn't there.

I don't think Congress thought the reason they didn't establish a procedure, maybe they should have and made it clear. But this material threat thing has a field that is well trod. You know, Ken Ellerbeck from the Soviet Union, Jessica Stern who was referred to by Congressman Weldon, the CDC, we know what the material threats are. Cyanide is not on it. It is recognized that cyanide is a material threat. What is taking so long?

Mr. PASCRELL. What would you do about the MTAs that are lasting 3 to 4 months? What do you think is the best response to that problem?

Mr. GREENBERGER. Frankly, I think it would be the chairman of the committee and the ranking member of the committee and the chairman of the subcommittee and the ranking member of the subcommittee getting on the phone with Mr. Chertoff and saying to him, this was never intended to be—this is the pivot on which the act operates, it is simple, get this done, we want it done by December 31, 2005.

Mr. PASCRELL. We are going to have the Secretary in front of us, the entire committee tomorrow. We should have some interesting debate or discussion, whatever.

Mr. GREENBERGER. You don't need legislation to fix this. Somebody has to say. I am sure if Mr. Chertoff, who I know and is a very intelligent, hard-working guy, this were explained to him—it is probably way below his pay grade but if he understood the whole statute was coming down because these assessments weren't being made he would have it done in a flash.

Mr. PASCRELL. Mr. Chairman, so many times we have had problems regardless of what issue we talk about in Homeland Security of moving the process along—I almost feel as if people are hesitant to make a decision to move the process along and that we are waiting for somebody else or they don't know who is supposed to make the decision.

Mr. WRIGHT. If I may, I believe that is a very good point. I believe the way the system was put together and using what was available was commendable at the time. But there is not a central person responsible. There is not a central department.

It falls in a number of departments, in a number of people's area of responsibility. And trying to coordinate this all has caused these problems. It is not just the MTAs and getting them out. It is the

length of time it takes to develop these drugs, and companies are going to have to expend hundreds of millions of dollars to meet these threats. They have to know that there is something at the end of the table.

If you look at the DOD process—as I mention in my testimony—the DOD has been buying and creating systems for years that there is no other commercial market for. They can't go out and sell an F-15 to anybody else. They have a process for doing that.

Mr. PASCRELL. You know, Mr. Wright, I am listening to you very carefully. I listened to all of you very carefully. There has got to be a difference between us developing a particular drug and us developing a particular antidote that is going to save people's lives.

We are asking guys and gals to go to Afghanistan and Iraq to defend the country. They are sacrificing every day, for whether we are for this war or against is immaterial. We support them. I want to know what sacrifices are going to be made on homeland to protect us.

So I know, we don't want to develop a drug that we are not going to get any response to and it is going to be hanging out there. But on the other hand, we all have responsibilities on this side as well as that side, to develop it. I am very concerned about us simply looking at product and how much this product is going to mean to the company in terms of the bottom line. The bottom line is, we all have a responsibility in this. If we meet it, if we can expedite, if we can lay down standards that make sense and move the anecdotal product to the front, then we will have accomplished something. I agree, we have been caught in a bureaucratic trap, which is not surprising, is it,

Mr. Greenberger?

Mr. MCCAUL. The Chair now recognizes Mr. Reichert for 5 minutes.

Mr. REICHERT. Thank you, Mr. Chairman. I just want to follow up on the latter question that the ranking member has been pursuing. We are getting the message loud and clear that there is a problem in DHS in coming up with a material threat assessment. Especially, Mr. Greenberger, you were very critical.

I would just like to ask you, in referring to Mr. Wright's comments about transparency and requirements and BioShield funding, do you agree with those three assessments as something that needs to be addressed?

The second part of that question is, are there any others that you would add to that list of three?

Mr. GREENBERGER. Well, yes, I agree. I focused on material threat assessments, because that is what your committee really has direct jurisdiction over.

Mr. REICHERT. Sure.

Mr. GREENBERGER. But there are a litany of problems with BioShield. Dr. Phillip Russell, who was the father of BioShield and has testified many times in front of committees, has listed problems, and one of those is transparencies.

It is a question of who is in charge here. Nobody knows where to go to and that is a very big problem. I agree, whether it is formally or informally, there needs to be a person who understands

the medicine and can work the bureaucracy to get these things ready and out there.

I do know that Dr. Fauci at NIAD, who is at the research end of this, and is giving out money for vaccines to be developed, I know this because the University of Maryland School of Medicine is the lead institution in that regard and I work closely with the center for vaccine development. They are making great strides in developing vaccines.

But all the research in the world—you have to do clinical trials, you have to have capitalization, you have to have laboratories. That is not being done. I think it is not being done because, unlike Dr. Russell, who understood all of this and what was needed, there is nobody in charge who understands how the science, the industry and the bureaucracies have to come together.

I am reminded in World War II we had a War Mobilization Board, and someone was put in charge of making sure that the country produced the products that we needed to defend ourselves. We have got lots of committees.

That is the trouble. Nobody knows which committee is in charge. The Weapons of Mass Destruction Committee, this committee, that committee, who is running the show? I truly believe no one is running the show. It may very well be because this is not on the top of the Secretary of HHS and the Secretary of DHS's primary focus. They have got much more immediate problems to worry about. So it should be worked from the top down and bottom up.

Mr. REICHERT. I wish you would just be honest and tell us what you really feel.

Mr. GREENBERGER. I have no vested interest here. I can tell you what I really think.

Mr. REICHERT. It was very clear, thank you.

Any other comments in regard to that question? Yes.

Mr. HOLLIS. Yes, in regards to expediency, when you are coming from the private sector like myself, we have invested tens of millions of dollars, over \$100 million already year-to-date in developing an acute radiation symptom drug. We were asked to develop this product by the Department of Defense. Here we are 4 years later and we still don't even have an RFP out for the nuclear threat.

This is really—I don't even know how that can be explained, but we are still waiting. We are in a real time scenario.

Mr. DICKS. Will the gentleman yield. Is that from Defense or DHS?

Mr. HOLLIS. That is correct. We have no request for proposal from DOD, HHS or DHS. We are in a real-time situation going through our FDA approval process. The product is being geared up to go through the peripheral efficacy trial for FDA approval. We have to commit to manufacturing, we have to commit a lot of money to get this drug approved.

We still don't know what the size and scope of the market power pursuing is. This is really unexcusable. I really believe I am putting a lot of the shareholder dollars at risk not even knowing what this market opportunity is.

Mr. REICHERT. Thank you.

I yield the balance of my time, Mr. Chairman.

Mr. McCAUL. The Chair recognizes Mrs. Christensen for 5 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chair. I thank you all for your testimony. I think it has been very, very informative, both the written and the oral testimony. I wanted to follow up on Mr. Greenberger's last comment.

Among the things he shared with us is that DFI International's summer, quarterly publication that suggests that we need a stand-alone biodefense agency to begin to really focus on these issues. The fact that it is—for example, biological defense is part of the chemical and biological defense program causes biodefense to have less priority as the programs are being developed and as budgets are being allocated.

So my question is, do we need a stand-alone biodefense agency or office? Would that help?

Mr. GREENBERGER. I am very hesitant to tell you that, because I am worried that every time we have a problem, the solution is a new bureaucracy. I think—I presume because of people like D. A. Henderson and Jerry Howard, who is sitting here. When they were at HHS, Dr. Russell was brought in to shepherd the BioShield program through and get it started. He has since left.

We need somebody of that caliber here to be given the lead opportunity to run this thing, for both Mr. Chertoff and Mr. Leavitt to say he is the person who is going to run this. That is a person who understands the research side, understands how you get to research to commercialization, knows how to run a bureaucracy and can knock heads together, all the legislation in the world.

I think this is not a partisan concern, it is a bipartisan concern, does not help if you don't tell the secretaries how important this is and to get somebody in there. If they do get somebody of that caliber in there, this can start to work, and you will get solid advice about what you need going forward in terms of legislative help.

Mrs. CHRISTENSEN. Anyone else?

Mr. WRIGHT. I actually believe that a single agency or department or whatever it is that is responsible for biodefense with the right resources in it would provide the right focus we need to get this thing done. I think with the number of different departments involved and the number of different people involved and the true lack of responsibility, which has been brought up a number of times here this morning, that there is no one you can go to and say make this happen and that person has the responsibility and resources to make it happen. I think it is a real, a real lack in the system.

Mr. HOLLIS. May I please add something to that? I think someone who is in that position would be beneficial. However, they also need to understand capital formation, because if we don't understand capital formation we are going to be dependent upon taxpayer and grant funding to get these medical products through.

Someone needs to be the voice to the capital markets that this is a very important sector, a biodefense sector and the government is committed to it so that investors are willing to take the risk and invest in companies that are developing medical countermeasures, because without that excitement there will be no investment in this area and there will be no medical countermeasures unless the gov-

ernment wants to fund the whole thing themselves and all the up front risk and research and development money.

Mrs. CHRISTENSEN. Go ahead.

Ms. WYSENSKI. I would just like to support both

Mr. Wright's and Hollis' comments in that we really do need to have one responsible source to receive direction from in a rather transparent way, and beyond that that we do have to deal with the very realistic consideration surrounding capital investment.

We are in the same situation, uncertain about what the demand for a cyanide antidote kit may be and at the same time estimating 2 to 3 years in advance for investments in a production facility. We are grappling with that issue as you speak. Until I can show the data about the potential size of the market, it is very hard for me to make a compelling argument for further investment in capital.

Mr. JOYCE. I would say one other thing that seems to be quite dangerous in these issues. The multitude of different parties involved is starting to turn this into a longer term perspective, that the countermeasures that we are talking about are countermeasures that need to be developed, that may not be on the market for 5 years, 10 years. It is an open-ended question.

Because there is not a single entity no one is really asking the question, what would we do if we knew there would be an attack with an unknown pathogen in the next 6 months? What countermeasures are available now and can be manufactured? There are treatments available now. There are things that are applicable to other viral conditions that can be developed now. One of the things that also needs to be analyzed is there seems to be a lot of focus on vaccine development.

Well, I think you need to closely analyze the history of vaccine development. Throwing money at vaccine development does not make vaccines appear. I am very familiar with the issues of HIV and AIDS. There has been a multitude of dollars, more than anyone is willing to throw at BioShield right now, spent in trying to develop a vaccine for the last 20 years. There is not one now and there is not one in sight in any time in the future.

So there has to be a focus on what countermeasures are there now, what treatments can be modified to be here in the coming months, not in 5 years or in 10 years. Thank you.

Dr. CARR. I would just like to end by saying I absolutely agree with that. There needs to be someone or someplace where they are beginning to address the potential near-term solutions, because vaccines and the development of them are not near-term solutions.

Mr. MCCAUL. The Chair recognizes Mr. Dicks for 5 minutes.

Mr. DICKS. Mr. Hollis, the drug you mentioned in your testimony, is it NEUMUNE?

Mr. HOLLIS. Yes, sir.

Mr. DICKS. That has not yet been approved by the FDA. That is the big problem here, right?

Mr. HOLLIS. No, well, we have an open I&D. We are going towards our pivotal trial and we are going towards FDA approval. However, BioShield is supposed to give you advance purchase contracts to give you the incentive to invest the dollars to develop the drug through the FDA approval process.

So if you are developing a drug through the FDA approval process and you have no idea of the size and scope of your market or a request for proposal, it is like asking a defense contractor to build a tank without knowing what the market is.

Mr. DICKS. What has been the problem? You said an advance purchase agreement?

Mr. HOLLIS. Yes, sir.

Mr. DICKS. What has been the problem in getting an advance purchase agreement?

Mr. HOLLIS. Well I think it is unanimous on this panel what the problem is—

Mr. DICKS. There is a material threat paper on this issue, right?

Mr. HOLLIS. You know, I am very glad you asked that. Because when we asked DHS about that, they said they had provided a national strategic nuclear threat assessment to HHS.

When we asked HHS where it was, they said they had not received an official risk assessment. But here we are 4 years into development and we still don't even have a request for proposal. As a consequence, our investors have lost confidence in the BioShield procurement process, and that is the reason we have almost a half a billion dollars loss in market capitalization because there is no transparency. The markets do not know what the government wants. When you ask me what the problem is, I really wish I knew, sir.

Mr. GREENBERGER. One point I might add is I do think the BioShield legislation—

Mr. DICKS. But let me on this point—just one second. DHS has done an MTA for the nuclear radiological, right? But they haven't given it to HHS.

Mr. HOLLIS. It is not an official risk assessment document that gives HHS the authority to go ahead and put this request for proposal out, is our understanding.

Mr. DICKS. So it is HHS that does the request for proposal, not Homeland Security?

Mr. HOLLIS. Yes.

Mr. DICKS. This is screwed up.

Mr. HOLLIS. Yes.

Mr. DICKS. So you think Congress should come up with an amendment, Mr. Greenberger?

Mr. GREENBERGER. Well, as I understand—

Mr. DICKS. We put somebody in charge, we can create a deputy secretary or an assistant secretary, someone, and say you are in charge and pass a bill to change the law and try to fix this?

Mr. GREENBERGER. Yes. I think that is a good suggestion. I would just warn you, as I understand BioShield II, the answer is to give this all to DHS. My—because—and I read the big pharma counsel's memo on this, because HHS is hostile to big pharma. Now, if DHS, now I am finding out we have been told there are material threat assessments for nuclear devices. Now I am told there may be but it hasn't been transferred to HHS. That is astonishing.

I think that you should be very leery of putting this in the hands of HHS certainly. I think HHS is the proper place for it, and I think if you want to have a deputy secretary or something for coun-

termeasures—and I agree the vaccines are not the only answer—then that would be very good and make that person in charge of making BioShield work. But right now I think what you are hearing here is nobody knows who is in charge, nobody knows what is going on.

Mr. DICKS. Mr. Hollis, again what happened to the Defense Department? I am on defense appropriations. What happened to them in this deal? Where did they fall on it or is it just the FDA thing that is still holding them up from buying something?

Mr. HOLLIS. Well, that is a separate department.

Mr. DICKS. Yes, we realize that.

Mr. HOLLIS. So I think they are more of an FDA issue because they are not operating under Project BioShield.

Mr. DICKS. The Defense Department?

Mr. HOLLIS. Yes.

Mr. DICKS. Are you still working with them?

Mr. HOLLIS. Yes, as a matter of fact are you familiar with AFRI, Armed Forces Research Institute. We are coordinating this product with AFRI. AFRI is one of our Nation's experts in radiobiology.

Mr. DICKS. How long do you think it will take to take get the FDA approval, in your judgment?

Mr. HOLLIS. I believe we can be on market next year. This is a real-time situation. We are actually looking at going into a pivotal efficacy trial this year.

Mr. DICKS. Efficacy trial, I take it that is a human trial?

Mr. HOLLIS. We are using the FDA's animal efficacy rule where it is unethical to expose human beings to lethal doses of radiation. You have to establish it in relevant animal models, in this case non-human primates, and then establish the safety in human beings.

Mr. GREENBERGER. One other point I think should be made is that the BioShield statute, if you get into this program, which starts at the material threat assessment and then moves on, the countermeasure can be used even if there isn't FDA licensing. The statute authorizes the Secretary of HHS to do this. But if you don't have a material threat assessment that gets you in the door, then you need FDA licensing.

Mr. DICKS. HHS. Material threat assessment at HHS?

Mr. GREENBERGER. No.

Mr. HOLLIS. No, it comes from DHS.

Mr. GREENBERGER. HHS does the MTAs.

Mr. DICKS. I know that, but I thought their argument was HHS had not seen it and HHS has to do the RFP.

Mr. GREENBERGER. That is correct. Because HHS must receive that, and then they can put in place everything that needs to be done to get these contracts out the door. If they don't get this piece of paper—and that is all it is, a piece of paper—they can't do anything.

Also, if DHS doesn't put cyanide or hemorrhagic fever, things that everybody recognizes are likely threats, I am for the MTA, even if the piece of paper goes to HHS, and it doesn't have those things on it, nothing can be done. Those people then have to worry about getting FDA licensing.

The anthrax—the \$1 billion spent with VaxGen’s anthrax countermeasure is only in clinical trials. It is way away from FDA licensing. So if you can get in the door here and get BioShield working for you, you can start laying out your capital plan because you don’t need all these things. They are looking for promising countermeasures.

Mr. HOLLIS. However, the process still takes too long because the understanding is that when HHS finally started to get the risk assessment here, they put out an RFI, a request for information. That was in October. We are here in July. Nine, 10 months later, they still have not put out an RFP.

That is a lot of time to look at a request for information before determining what the request for proposal is. So this loss of time is really a killer in an industry because you can’t put out your capital plan in developing the product.

So what I want to ask this committee, not only for acute radiation syndrome but any other medical countermeasure, is they need to put these RFPs out to industries so that we know what our size and our scope of our market is and we can respond.

Mr. DICKS. One final thing, Mr. Chairman.

Mr. MCCAUL. That is fine.

Mr. DICKS. Just to wrap this up. I want to make sure I understand this now. You said that—who could give FDA, FDA-like approval, the Secretary could?

Mr. HOLLIS. There is emergency use authorization provision. It is called the EUA. If the Secretary determines that—

Mr. DICKS. Which Secretary?

Mr. HOLLIS. The Secretary of Health. Determines that the benefit of having an identified drug outweighs the risk because of the nature of the threat, they can actually procure the drug before it is FDA approved.

Mr. GREENBERGER. Yes. I would just amend that to say they could use the drug short of an FDA approval if they make these emergency findings, they being the Secretary of HHS. But they can purchase the countermeasure before an FDA approval too. That is even more important.

VaxGen’s promising anthrax vaccine is a while away from approval but \$1 billion has been spent to purchase it. Now obviously when we are talking about forming capital markets, VaxGen’s shareholders are pretty pleased with that. They know they are going to get \$1 billion. All of these other people are sitting up here with what they think are great countermeasures and they can’t even get in the door because DHS hasn’t started the process by making a material threat assessment for cyanide or hemorrhagic fevers. If they did, then these people could start, if they knew who to go to, start marketing it if they wouldn’t have to worry about FDA, because you can get a BioShield contract without FDA approval.

Mr. DICKS. Well, do you think this is being done simply to stop the money from being spent or is it just complete negligence?

Mr. GREENBERGER. There could be an argument—and I think somebody raised that—that they don’t think they have enough money to buy all the countermeasures, so they are going into a four corners offense to slowly dribble it out.

After all, they have had one major contract for \$1 billion. That means 15 percent of the money is already gone. If there are, as I think there are, at least three dozen candidates to be material threats, they may be saying to themselves, whoa, we are going to lose this 5.6 before it happens.

Ms. WYSENSKI. If I could—

Mr. GREENBERGER. If I could respond for a second to that thought. Because you have got to believe that a lot of people who appear at the door with effective measures for hemorrhagic fever, for pandemic flu, Congress may start thinking it may be worth appropriating more than 5.6 if we have got real solutions here. So if that is what they are thinking, that doesn't make a lot of sense.

Ms. WYSENSKI. It seems to me that one method to really force a change in this whole process is to show some quick wins to the public and to private industry. In fact, we do have low hanging fruit that can easily be turned into a quick win for the government and for government industry.

At EMD, we are in the same situation that Mr. Hollis explained. We are nearing completion of our animal studies, because, of course, you can't subject humans to these trials. We have completed the safety work, we are negotiating with the FDA. We are preparing to submit the MDA.

We are going on pure faith to Mr. Pascrell's earlier comment that the government will continue to work with us, because in fact we are getting ahead. Until that MTA is done and the purchase order can then hopefully be produced in a somewhat timely manner, we are really putting these investments down at this point at risk.

Mr. DICKS. This is your cyanide?

Ms. WYSENSKI. Yes, sir.

Mr. DICKS. Thank you for being so generous, Mr. Chairman, I appreciate it.

Mr. MCCAUL. Thank you. Are there any other members that have additional questions at this time. I would like to thank the witnesses for their valuable and very insightful testimony and the members of the committee may have additional questions for you to submit in writing.

This hearing record will be open for 10 days. Without objection, the committee stands adjourned.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned.]

FOR THE RECORD

JOHN VITKO RESPONSES TO THE HONORABLE MIKE ROGERS QUESTIONS

Question: 1. Does the Department of Homeland Security consider Avian Influenza a potential threat? If yes, did Congress grant authority through Project BioShield to the Department of Homeland Security to address the threat of Avian influenza?

Response: The Department of Homeland Security views the natural emergence or intentional introduction of a highly pathogenic influenza strain as a potentially serious public health risk. If a strain emerges naturally and acquires human-to-human transmissibility, there is the potential that terrorists might use this strain as a bio-terror threat agent.

The Project BioShield Act of 2004 authorizes the Homeland Security Secretary in consultation with the Secretary of the Department of Health and Human Services (HHS) and the heads of other agencies to assess current and emerging threats, including biological agents. We interpret the legislative language to be sufficiently broad enough that the Secretary of Homeland Security has the authority to issue

a material threat determination for any strain of influenza that poses a threat to the United States population sufficient to affect national security.

Question: 2. Has the Department of Homeland Security funded, through Project BioShield, research and development of therapeutic drugs to address potential bio-threats?

Response: Although the Department of Homeland Security is critically involved in establishing and prioritizing the medical countermeasure requirements for acquiring medical countermeasures utilizing the BioShield Special Reserve Fund, it is HHS, through the Office of Public Health Emergency Preparedness, that is charged with actually making such procurements. To date, the Project BioShield Special Reserve Fund has already been used by HHS to contract for a second generation anthrax vaccine (rPA), additional quantities of the current anthrax vaccine (AVA), and a pediatric formulation of potassium iodide (for certain radiological/nuclear exposures). HHS is in the midst of procurement actions for additional countermeasures including anthrax therapeutics and a next generation smallpox vaccine (MVA). All these procurement actions are for vaccines and therapeutics that are relatively far along in the developmental pipeline so as to meet the statutory requirement that there is “sufficient and satisfactory clinical experience or research data (including data, if available from preclinical and clinical trials) [to] support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years”. The Project BioShield Special Reserve Fund is not meant to fund, nor has it funded, any early stage R&D. The appropriate funding source for early stage R&D is the research funding appropriated to the National Institutes of Health (NIH) through the traditional appropriations process. However, the Project BioShield Act did provide mechanisms for streamlining and expediting the solicitation, acquisition, review, and award process used by NIH to support such projects, and NIH has begun using those authorities.

Question: 3. Can Project BioShield fund research for medical countermeasures in order to anticipate potential pandemic threats?

Response: As noted above, the Special Reserve Fund created under the Project BioShield Act is only for the procurement of medical countermeasures that are in advanced development and can be reasonably expected to qualify for approval or licensing within eight years. Early, or even mid-stage research is to be funded through the NIH research program and not the BioShield Special Reserve Fund. In an effort to accelerate this research, the Project BioShield Act did however streamline the peer review process used by NIH in evaluating and selecting such projects.

